

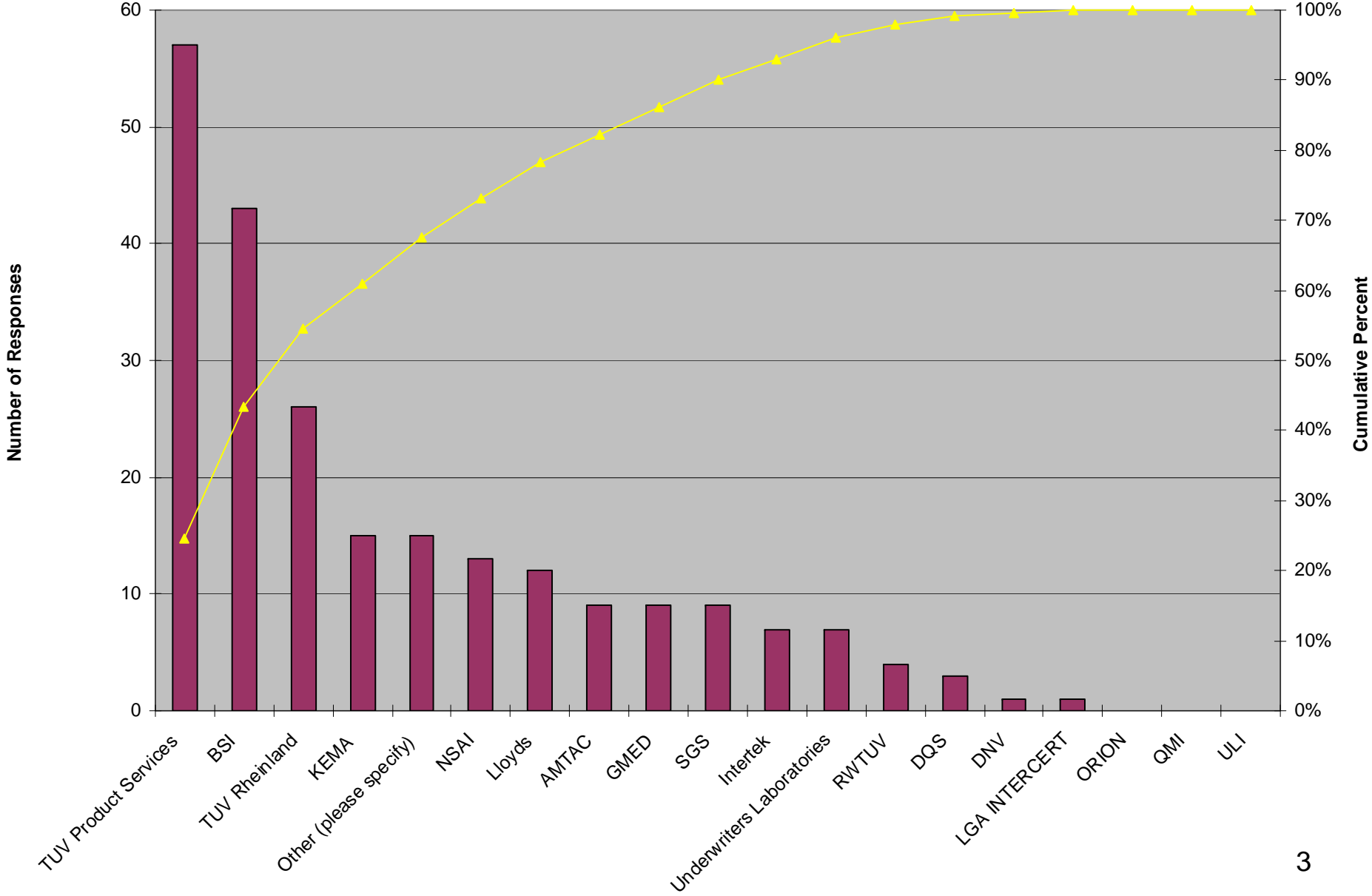
Results from the Notified Body Survey

Sponsored by
Nancy Singer
Compliance-Alliance
www.compliance-alliance.com

Notified Body Survey

- Compliance-Alliance conducted a survey to compare medical device firms' satisfaction with various notified bodies.
- 242 individuals responded to the survey.
- The bar graphs that follow show the responses

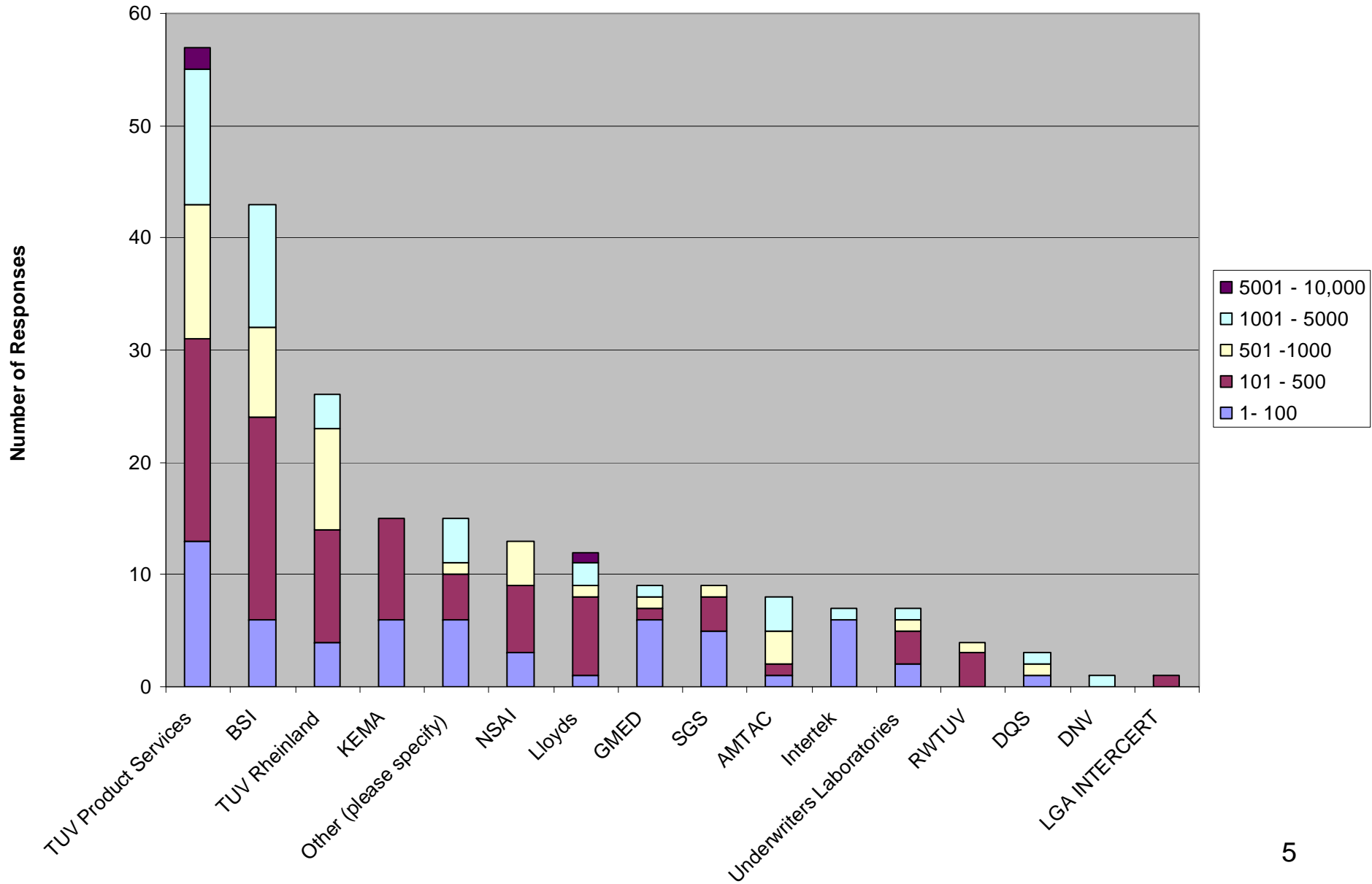
Who is your firm's current notified body?



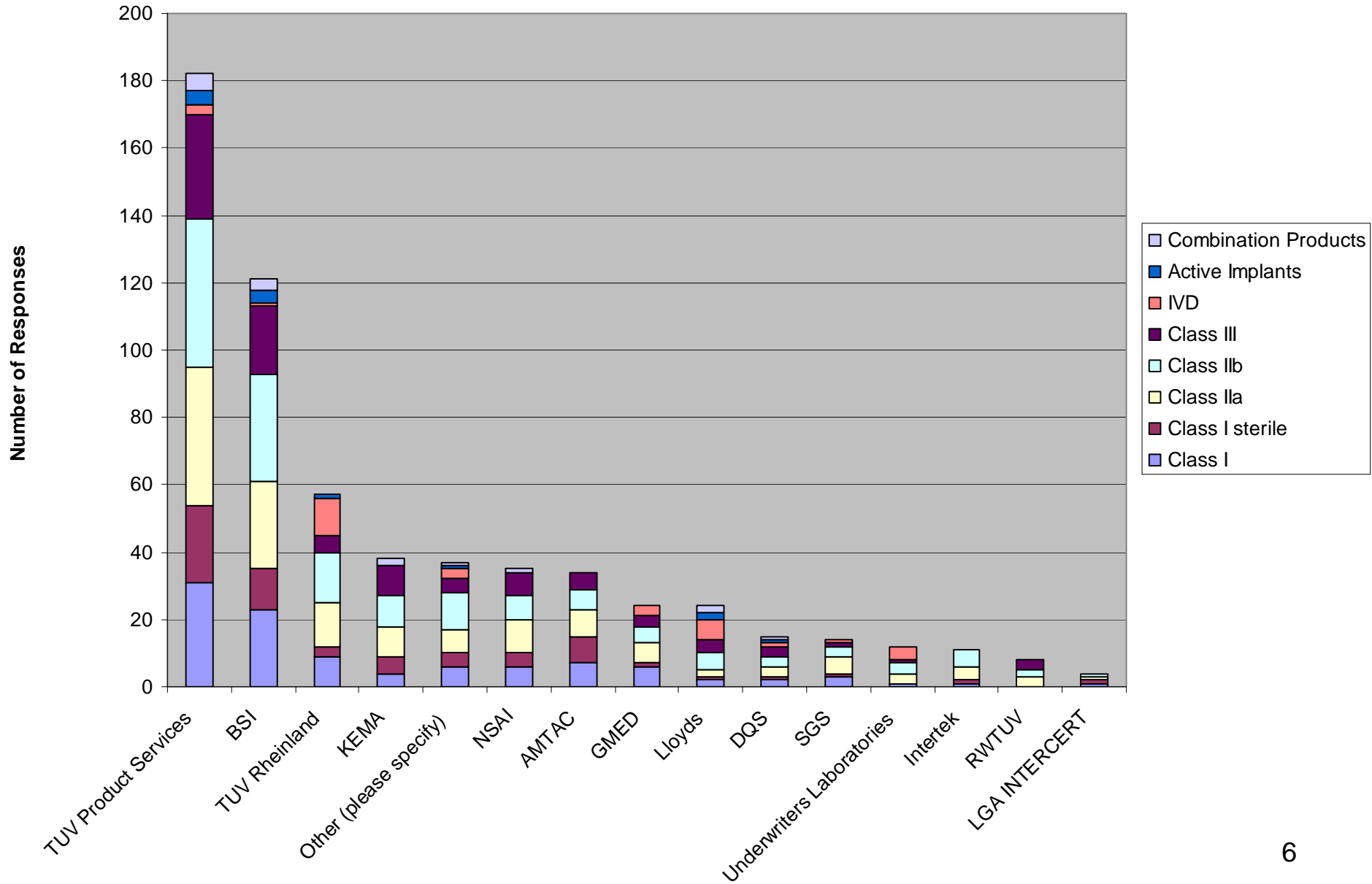
Key

- For the graphs in slides 5 – 36:
 - Each of the colors of the charts represent a particular choice in responding to the question.
 - Use the numbers on the left of the bar graph as a ruler to measure the number of responses.

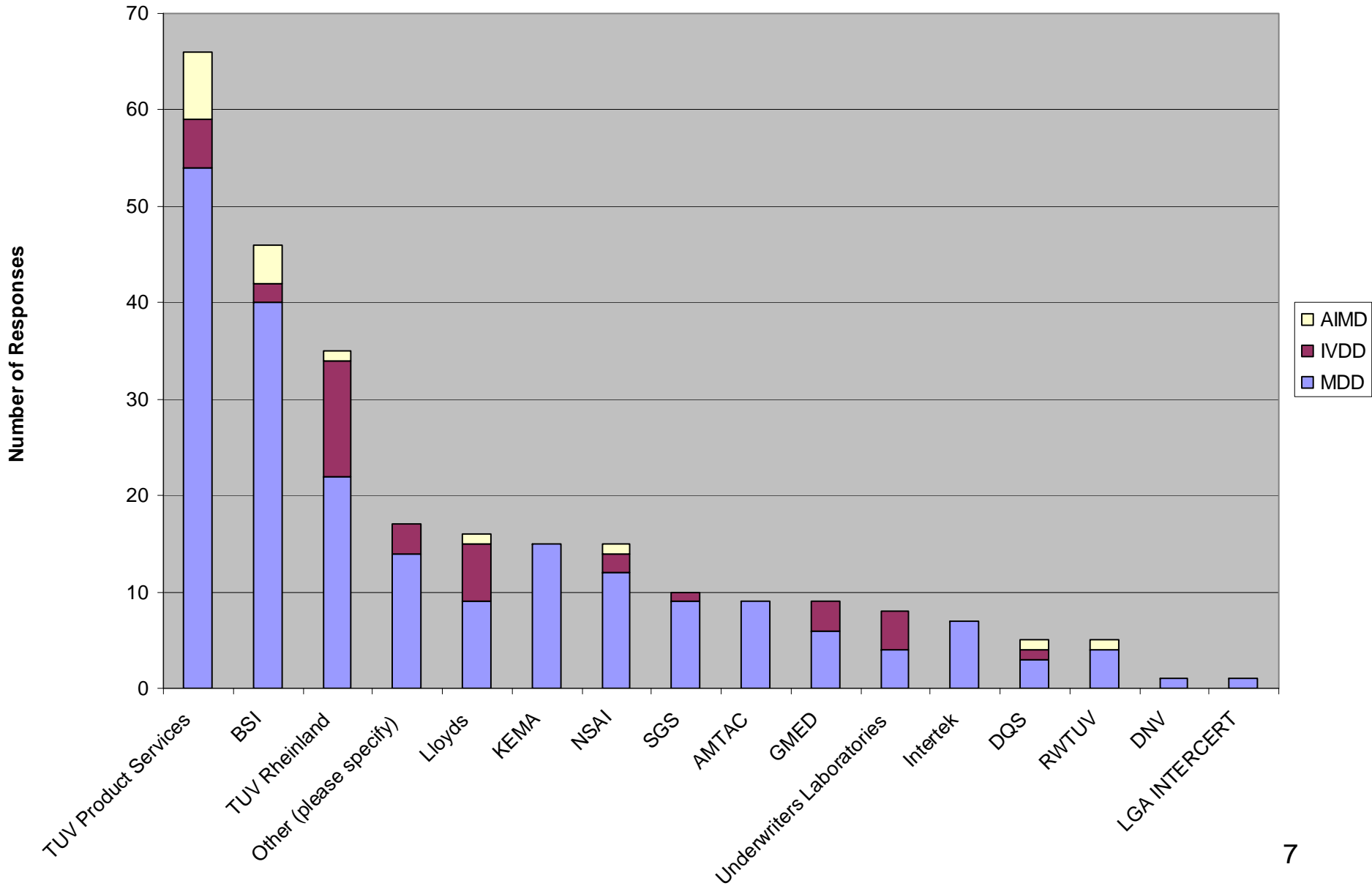
How many people are employed at your current location?



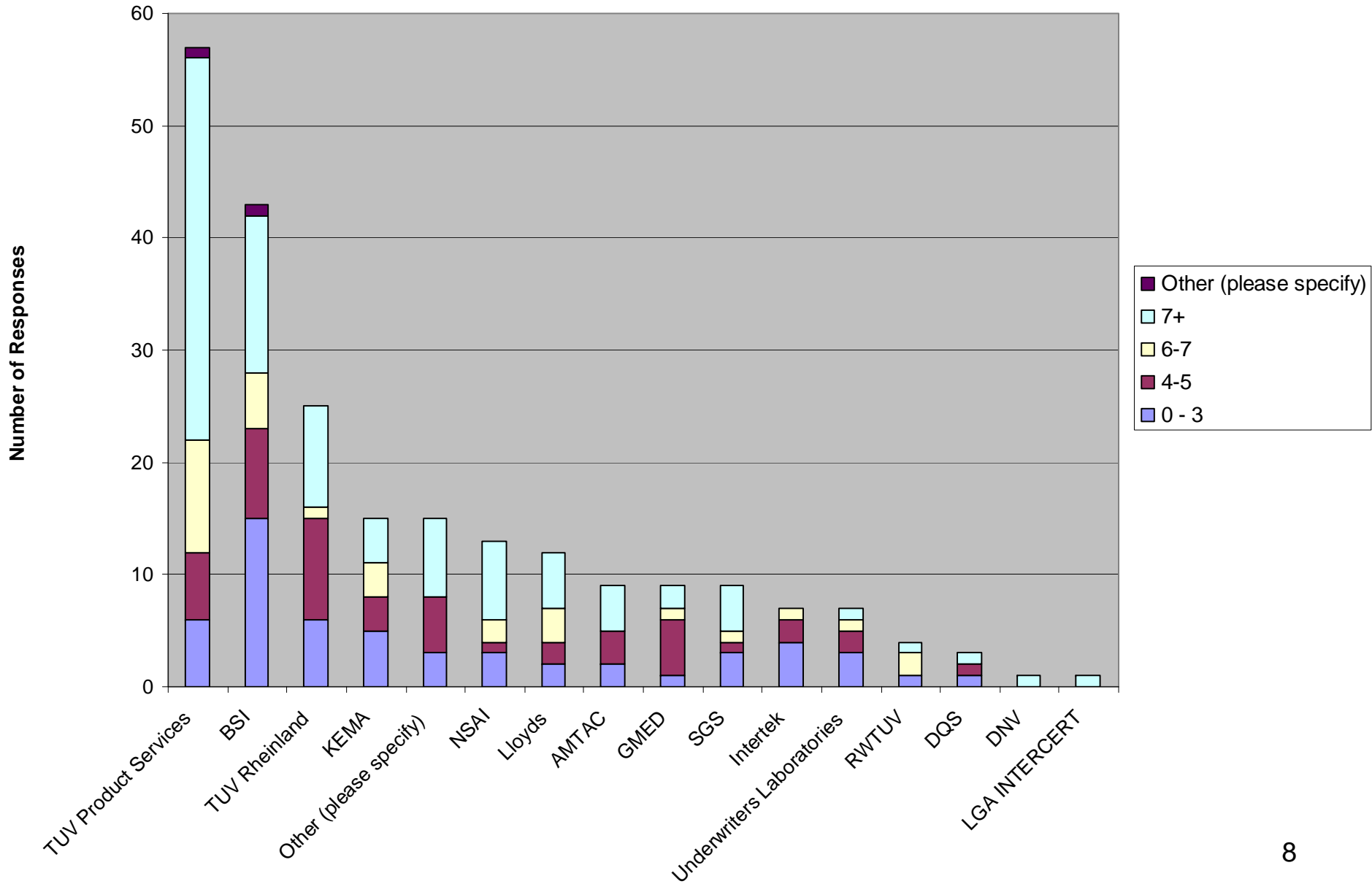
What MDD class devices does your firm market (select all that apply)?



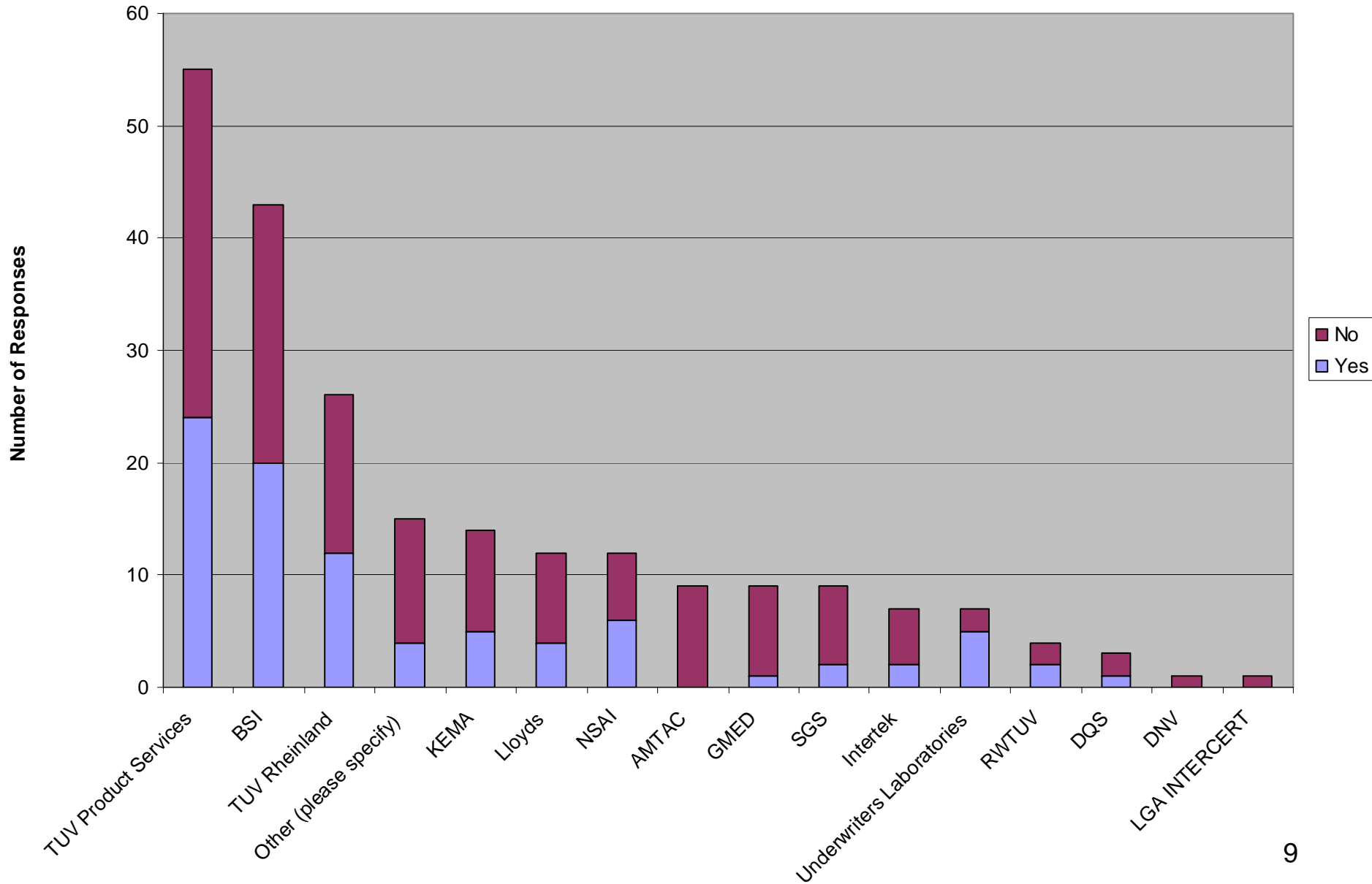
What directive(s) apply to your firm (select all that apply)?



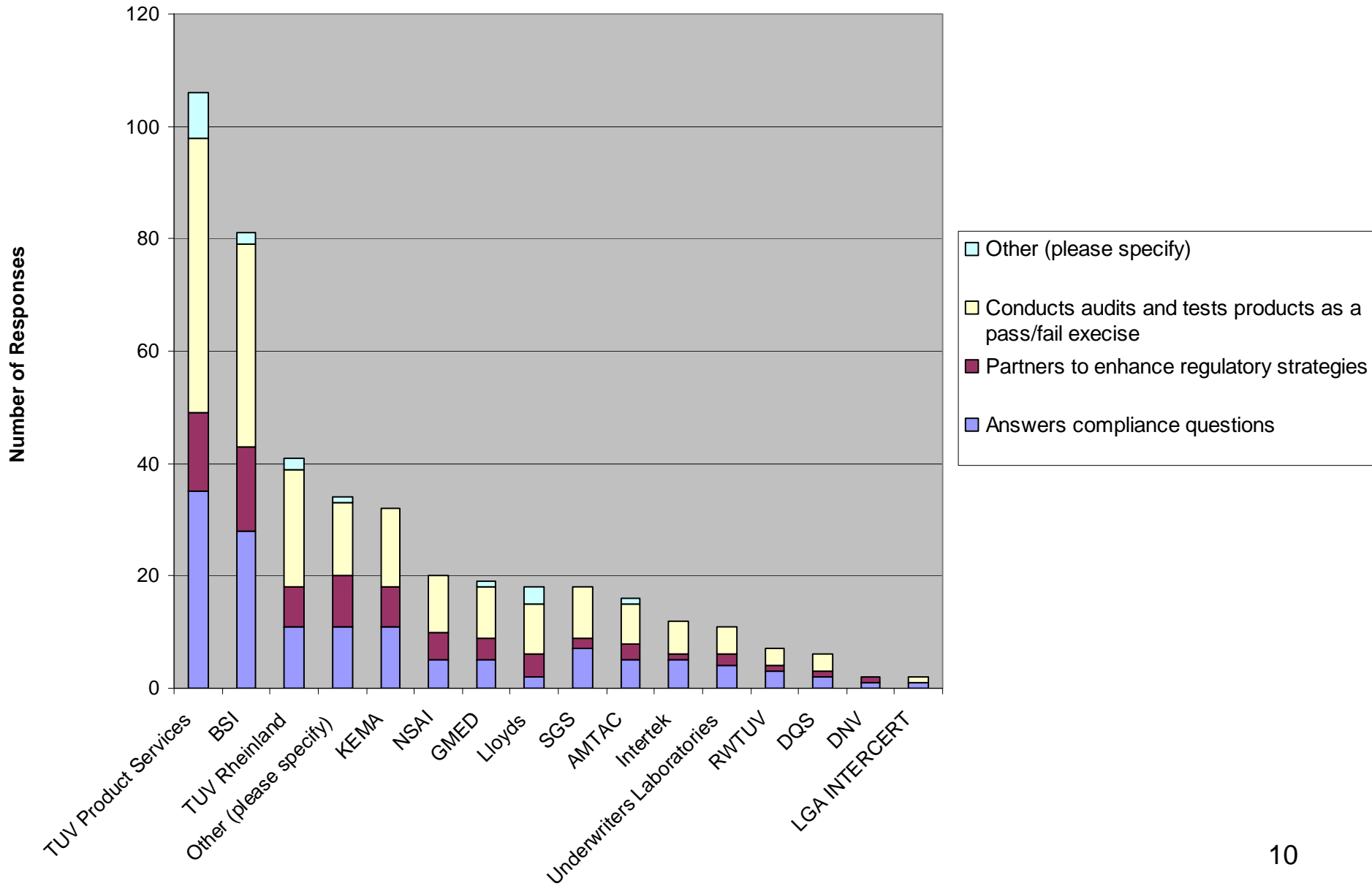
How many years have you been working with your current notified body?



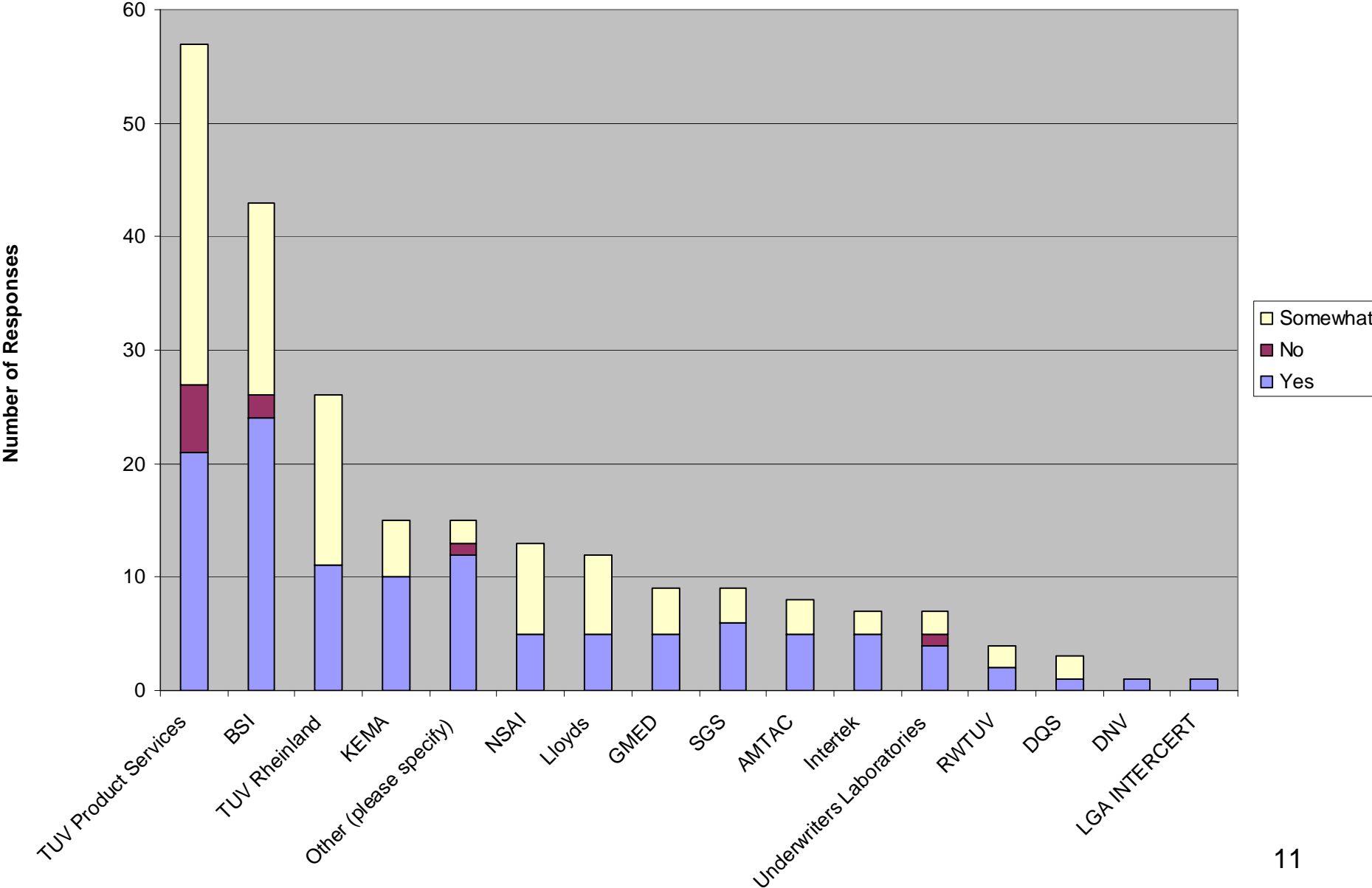
Is your site located in the same country as your notified body?



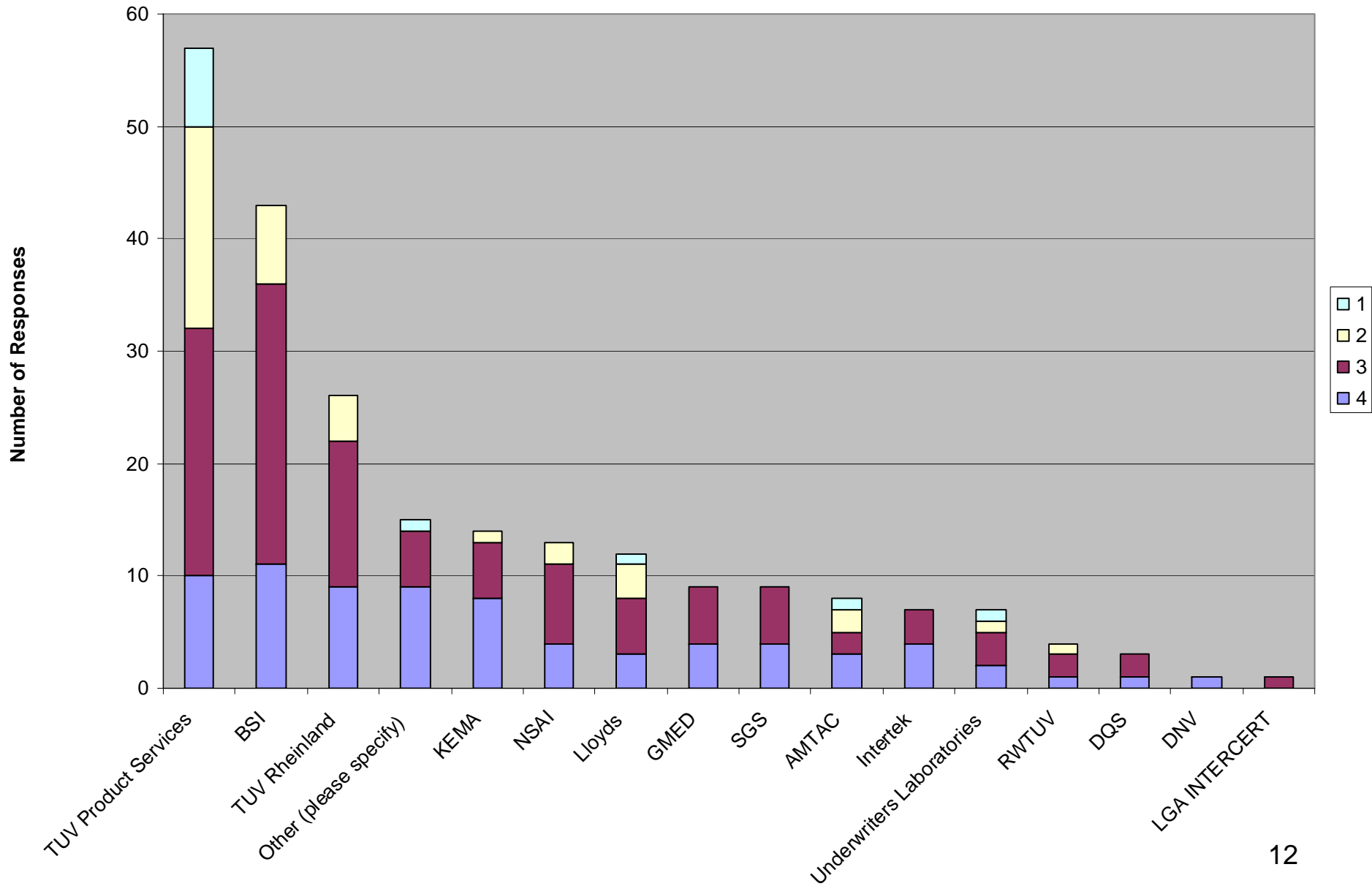
How does your notified body work with your firm? (Check all that apply.)



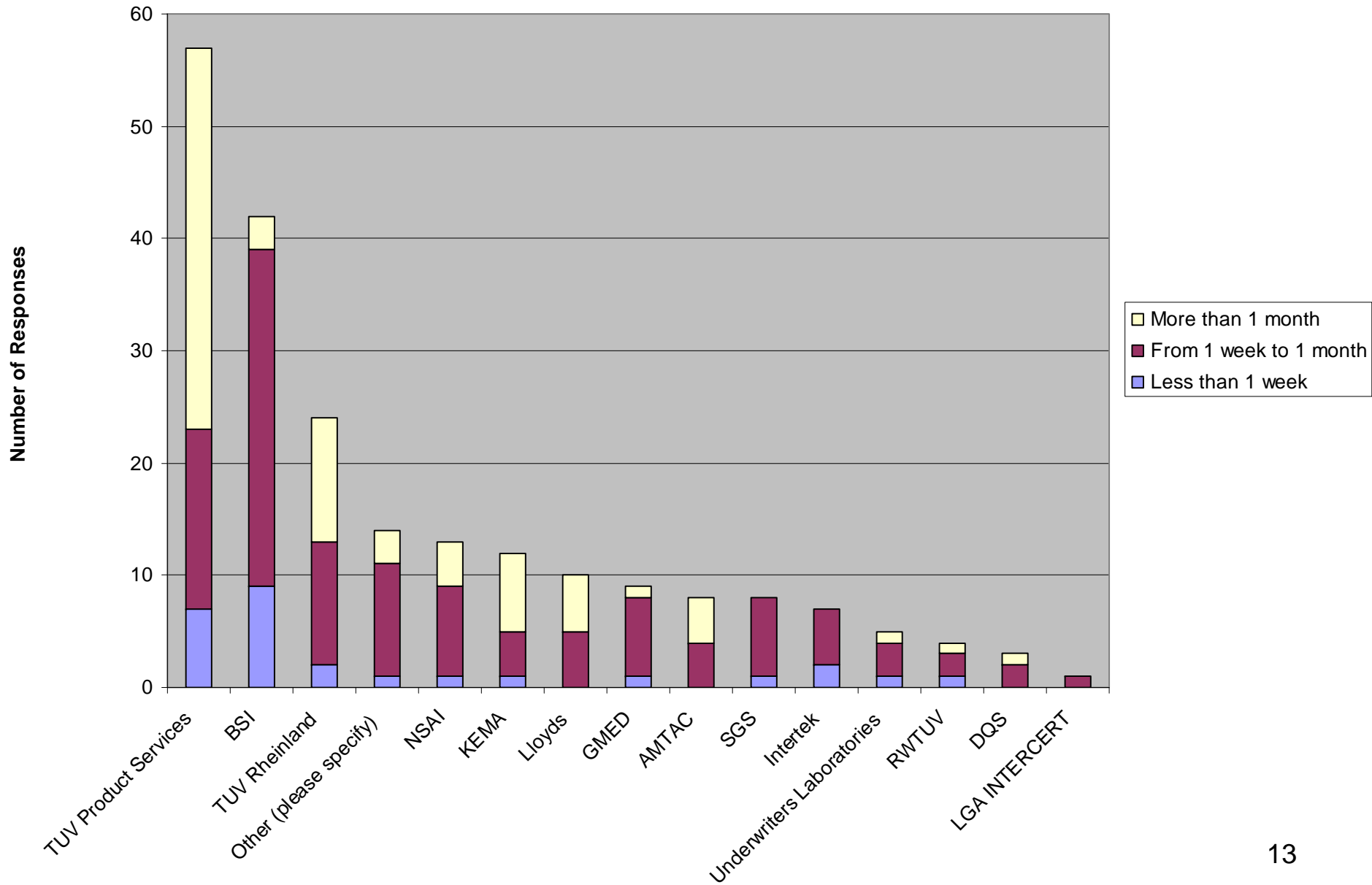
Are the auditors knowledgeable about your products and business goals?



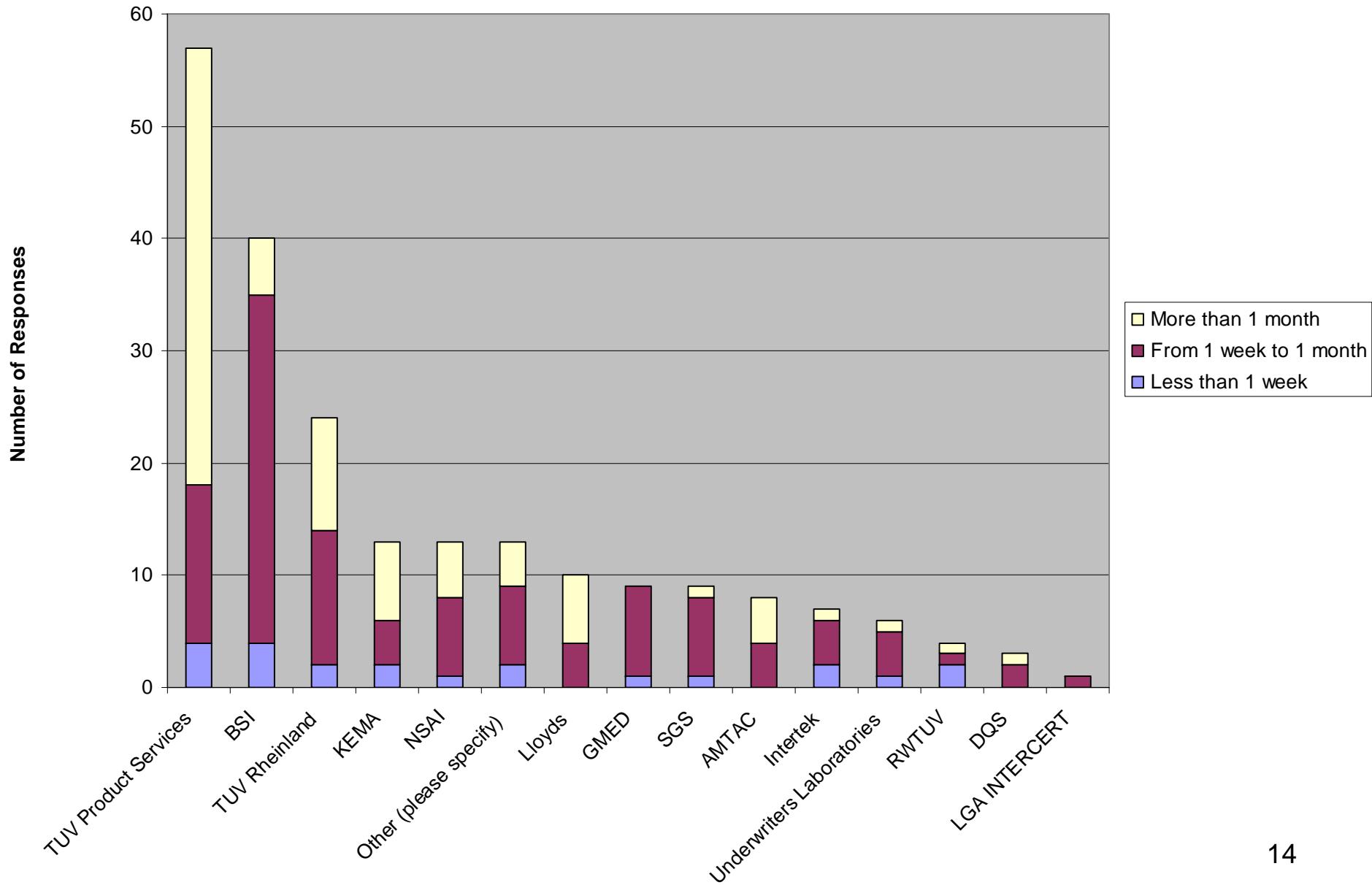
On a scale of 1 to 4, with 4 being very strong, rate how strong your auditor is on his/her skill sets.



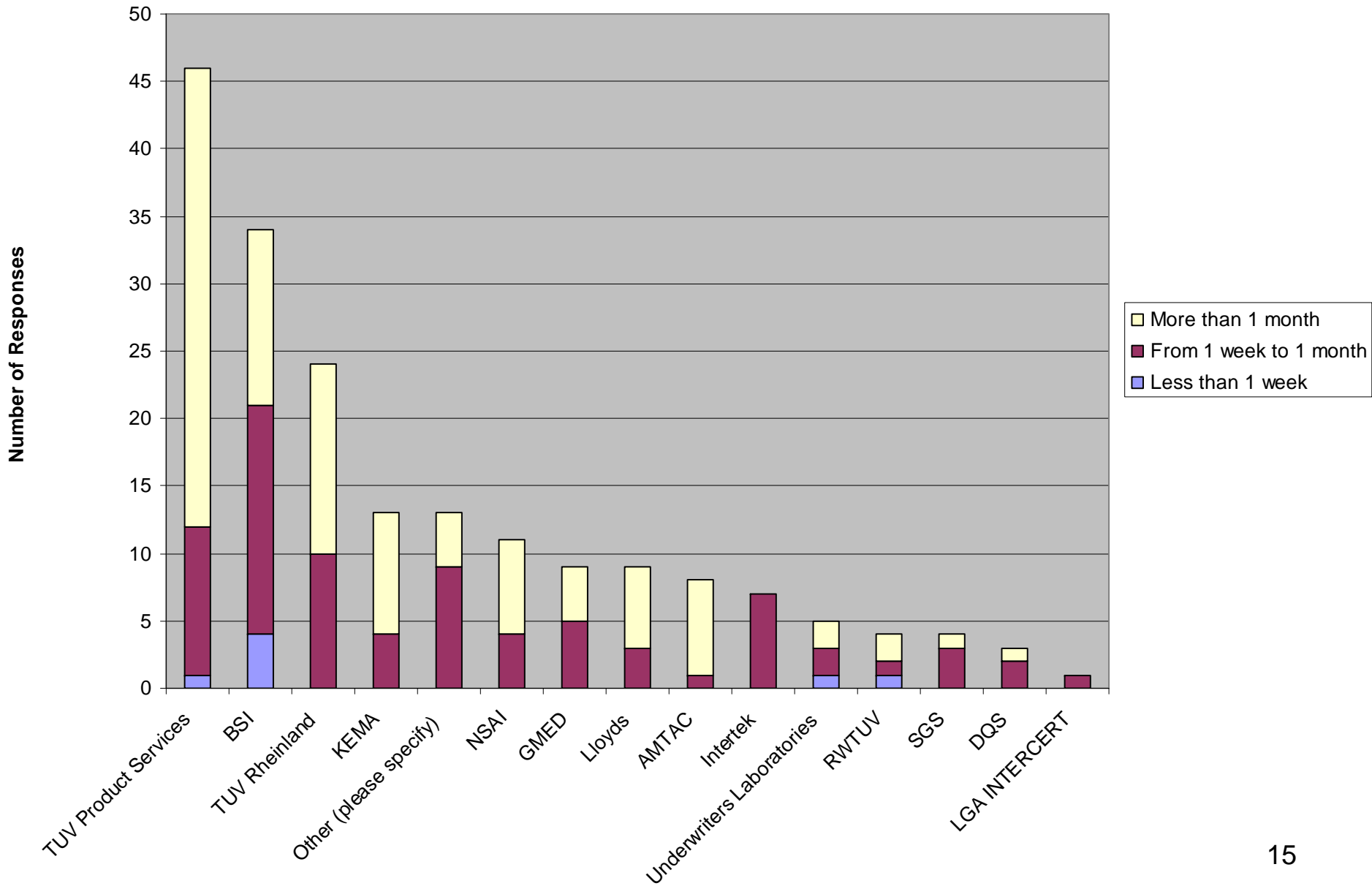
On average, how quickly does your notified body respond to quality system change notices?



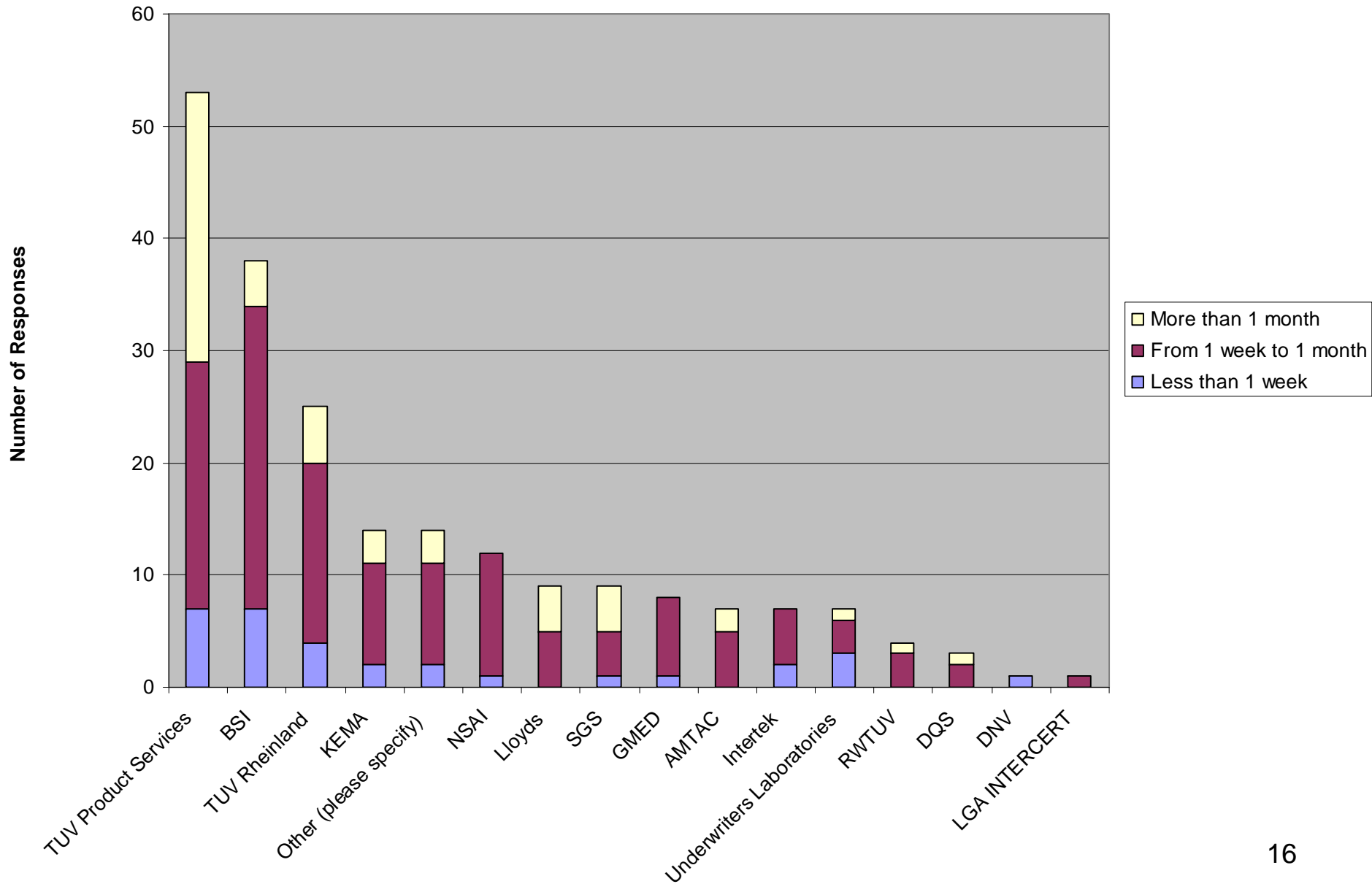
On average, how quickly does your notified body respond to product scope change notices?



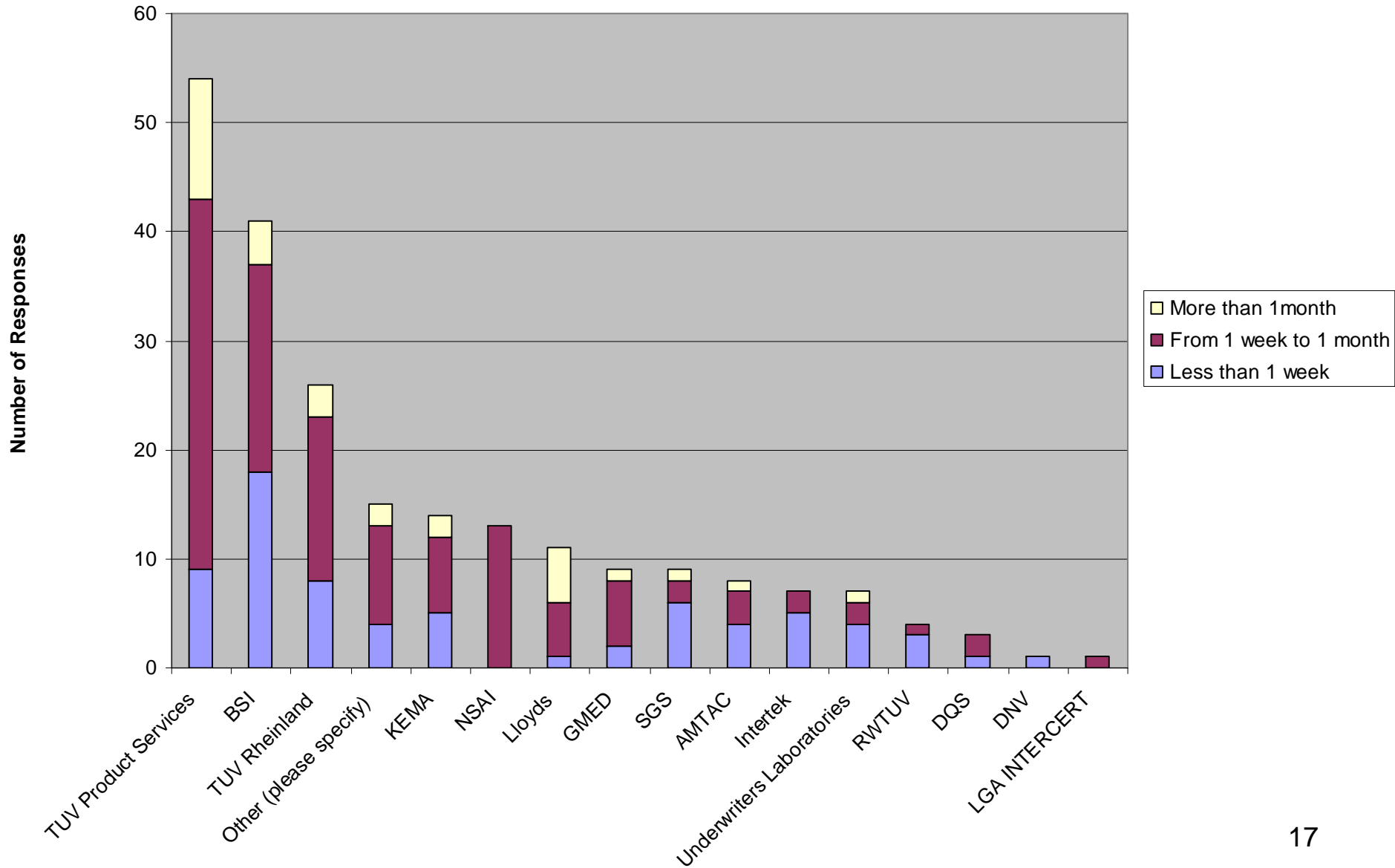
On average, how quickly does your notified body respond to dossier reviews?



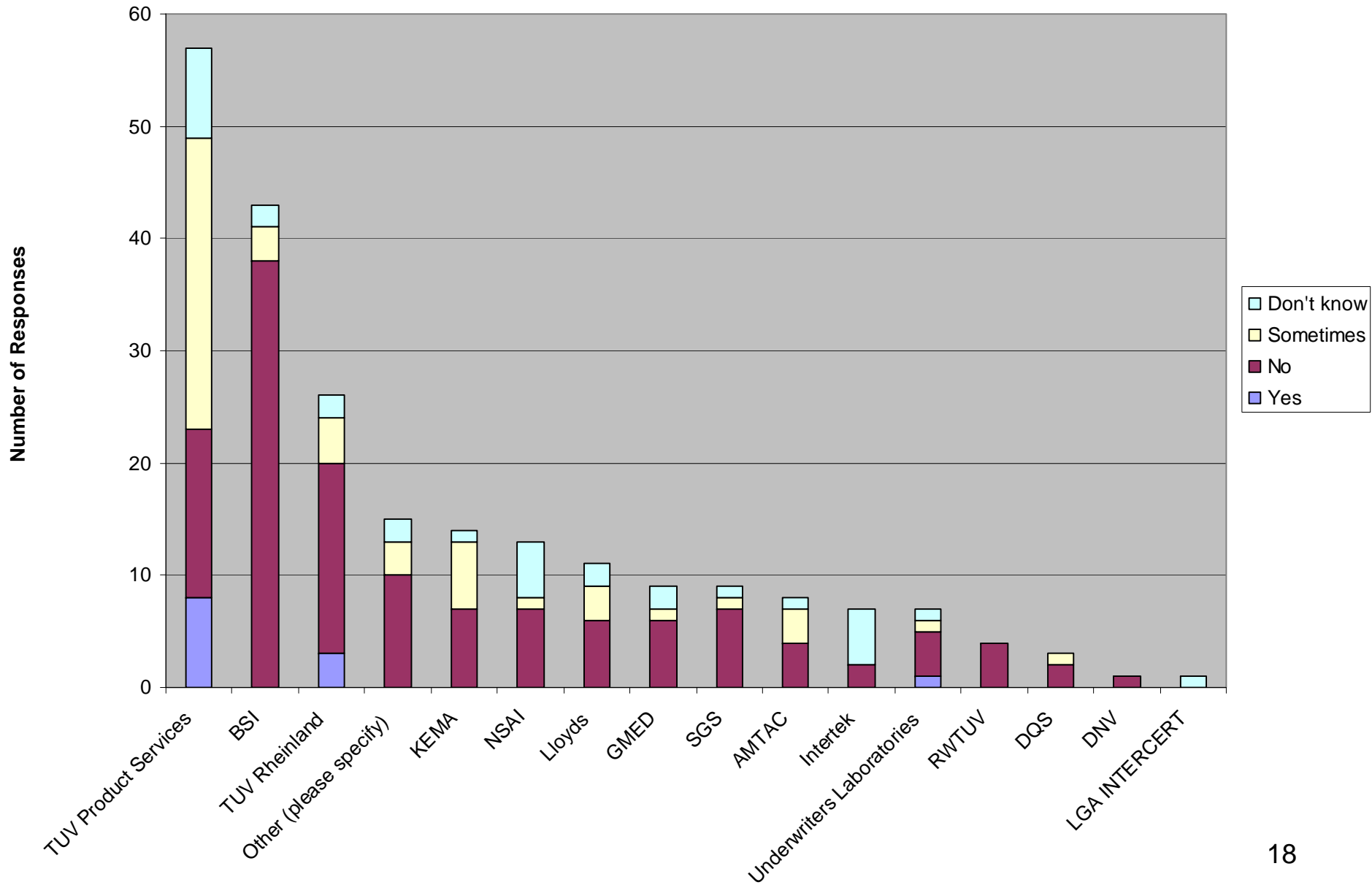
On average, how quickly does your notified body respond to corrective action responses?



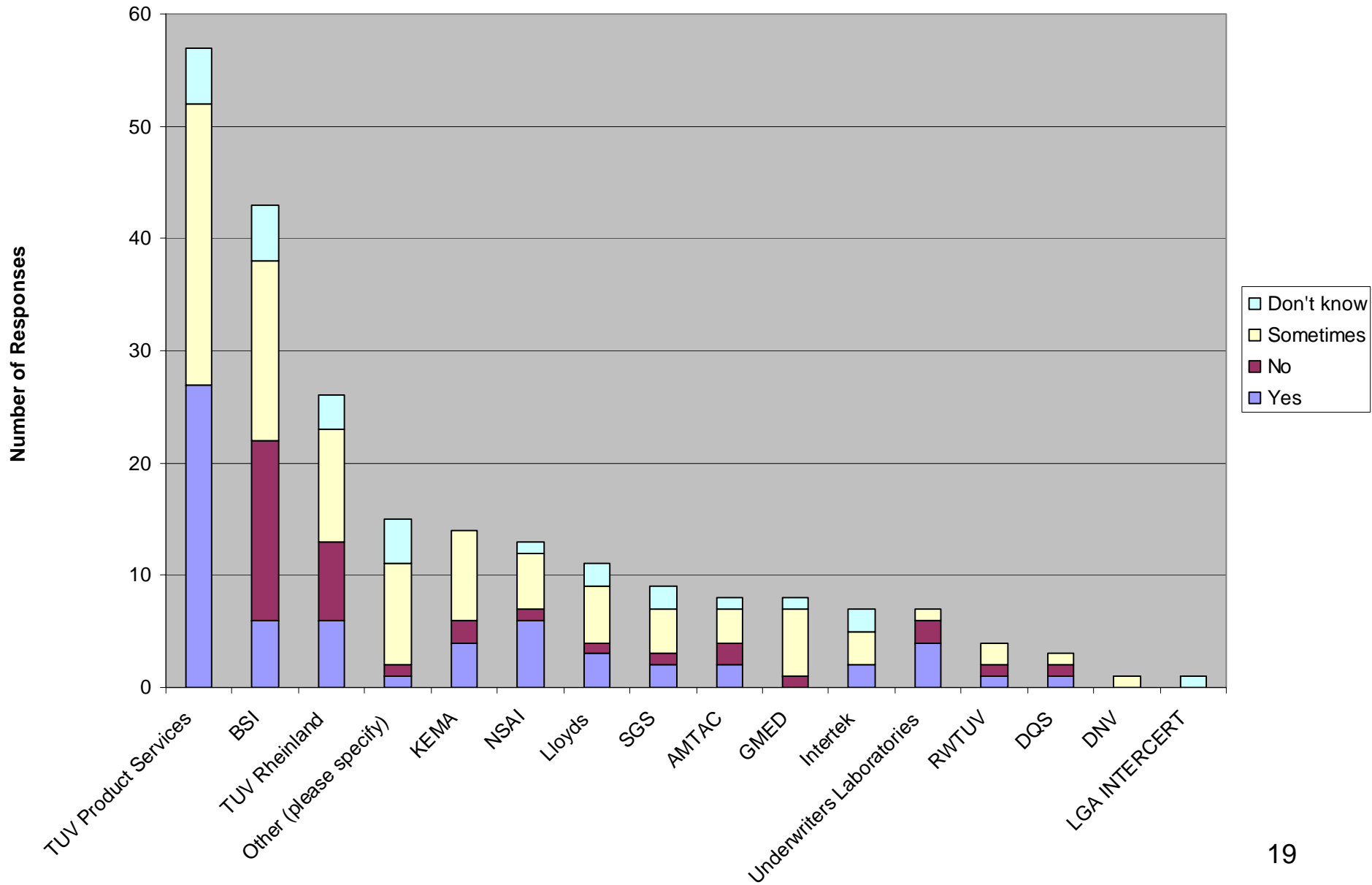
On average, how quickly does your notified body respond to general product or quality system questions?



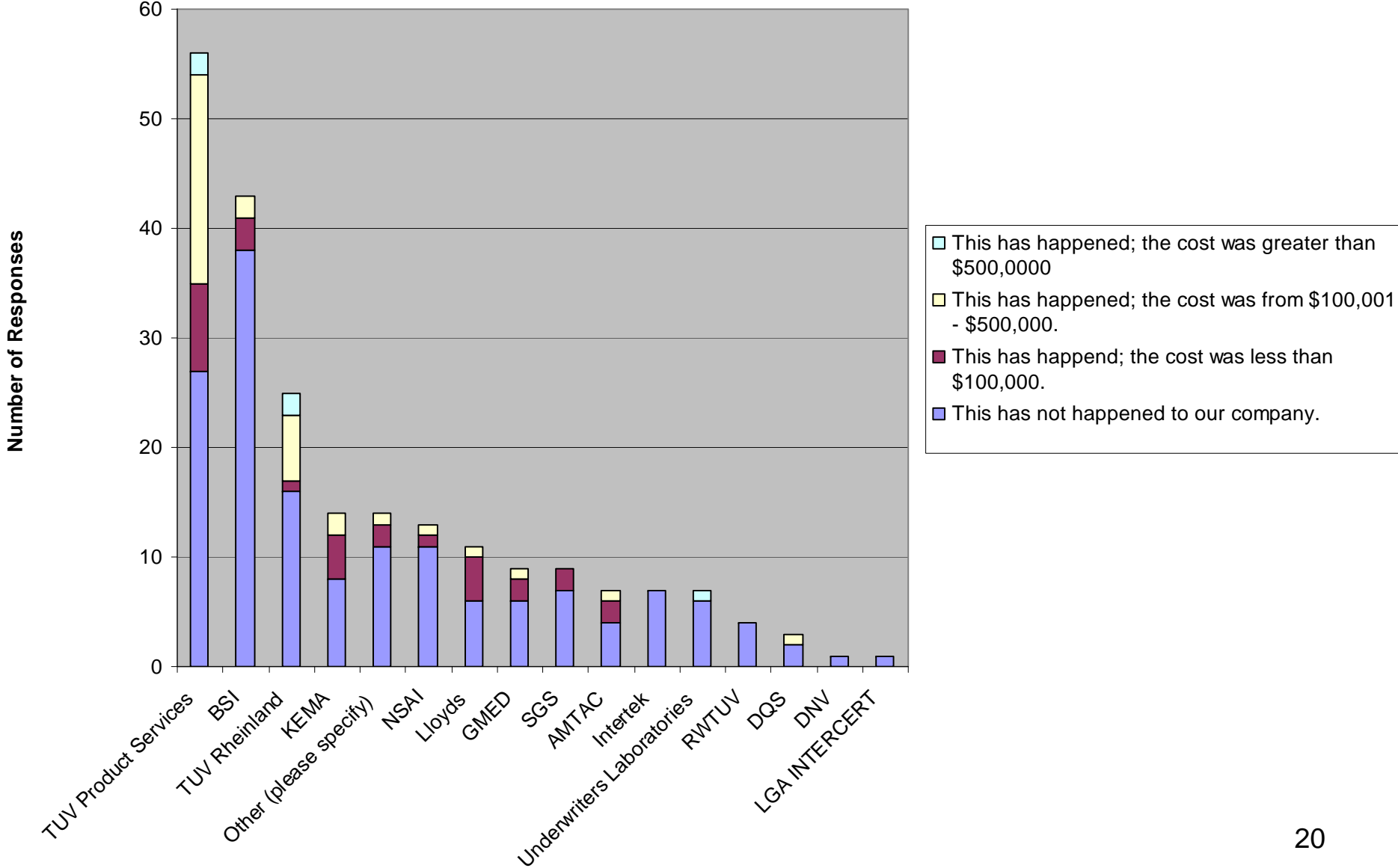
During inspections does your notified body apply unapproved guidance documents?



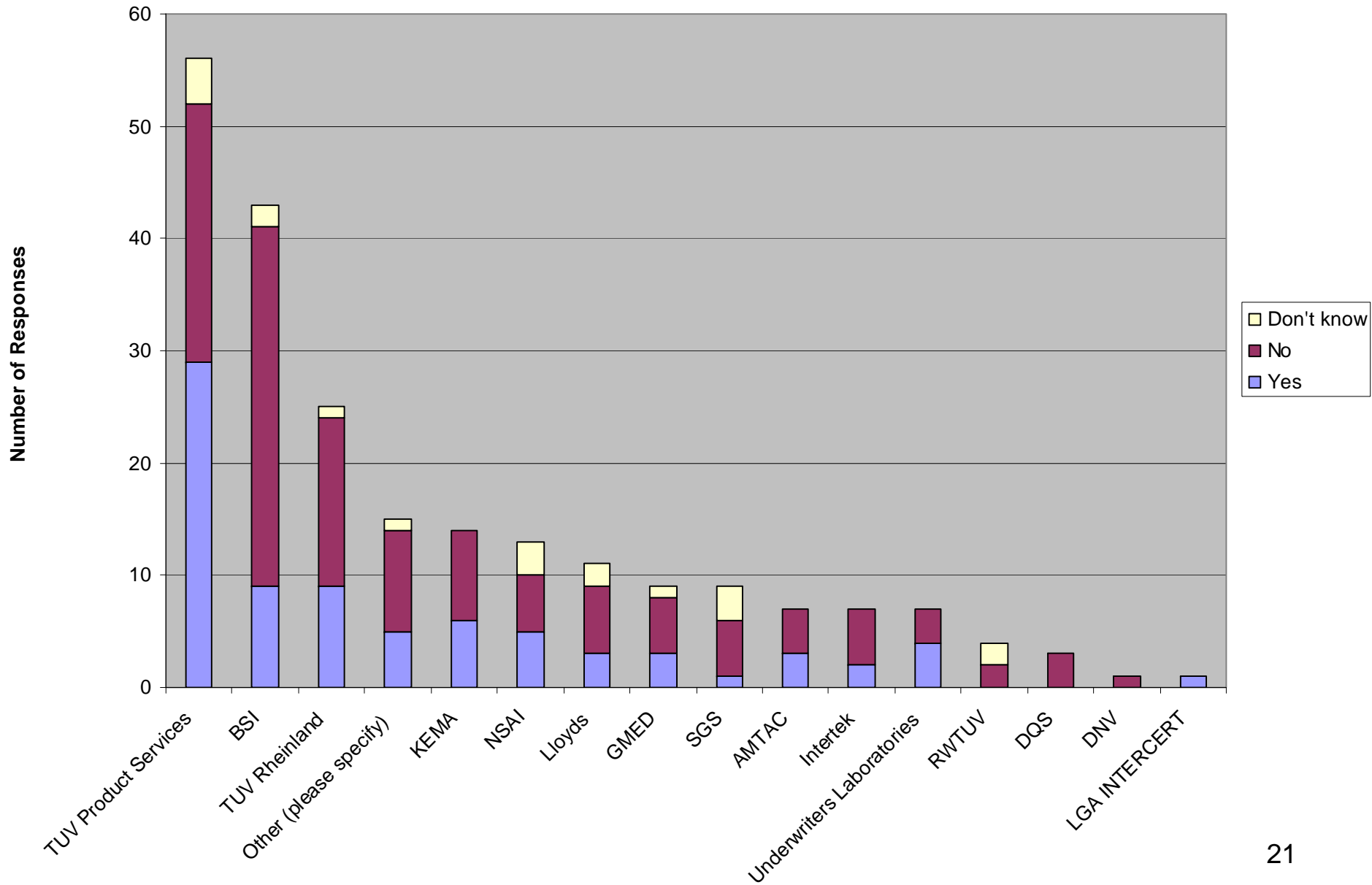
During inspections does your notified body use its own interpretation of standards?



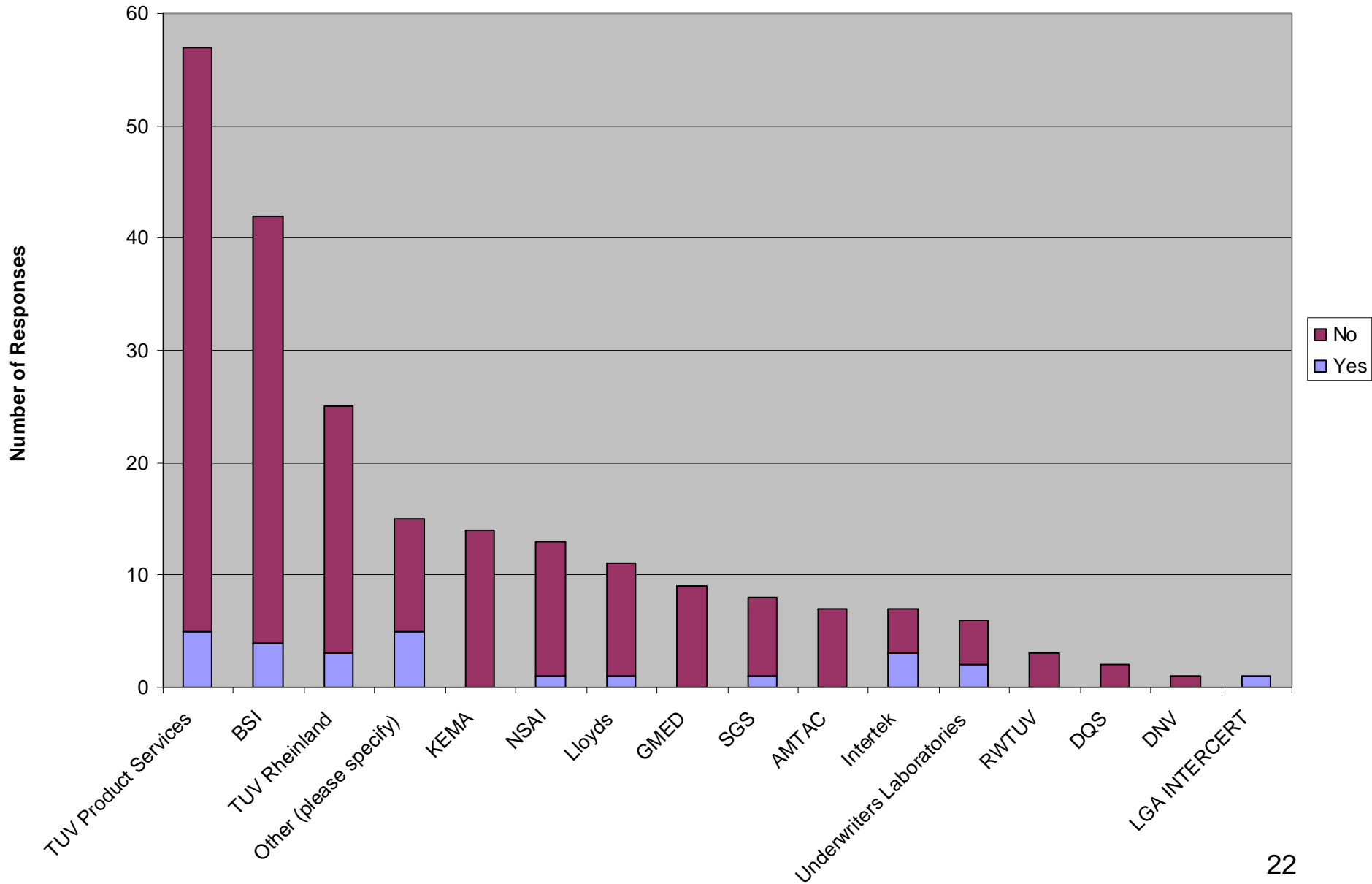
Has your notified body review time ever negatively impacted on new product launches or sales, and if so please estimate the business loss?



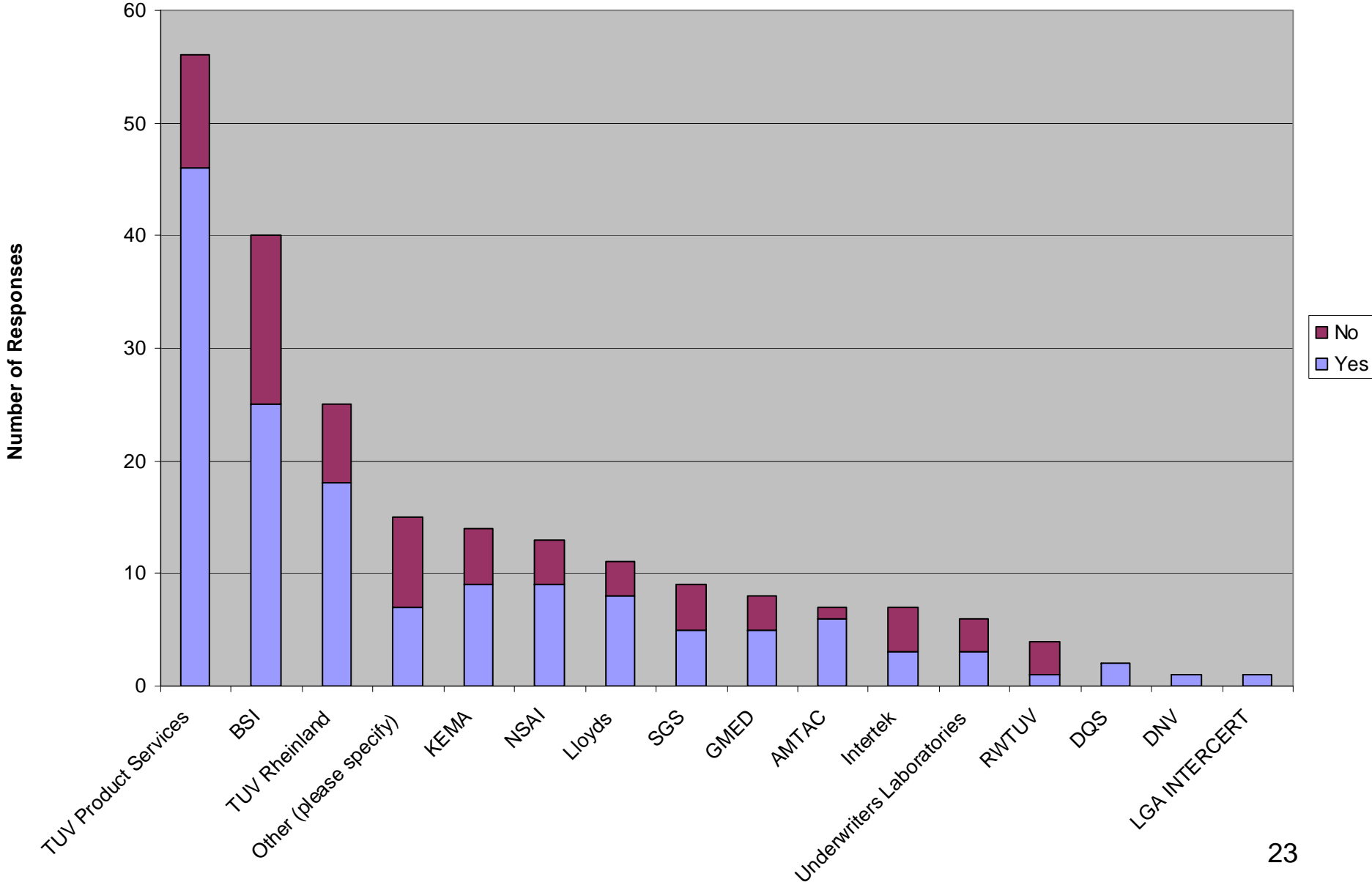
Has your firm ever formally challenged the findings of your notified body?



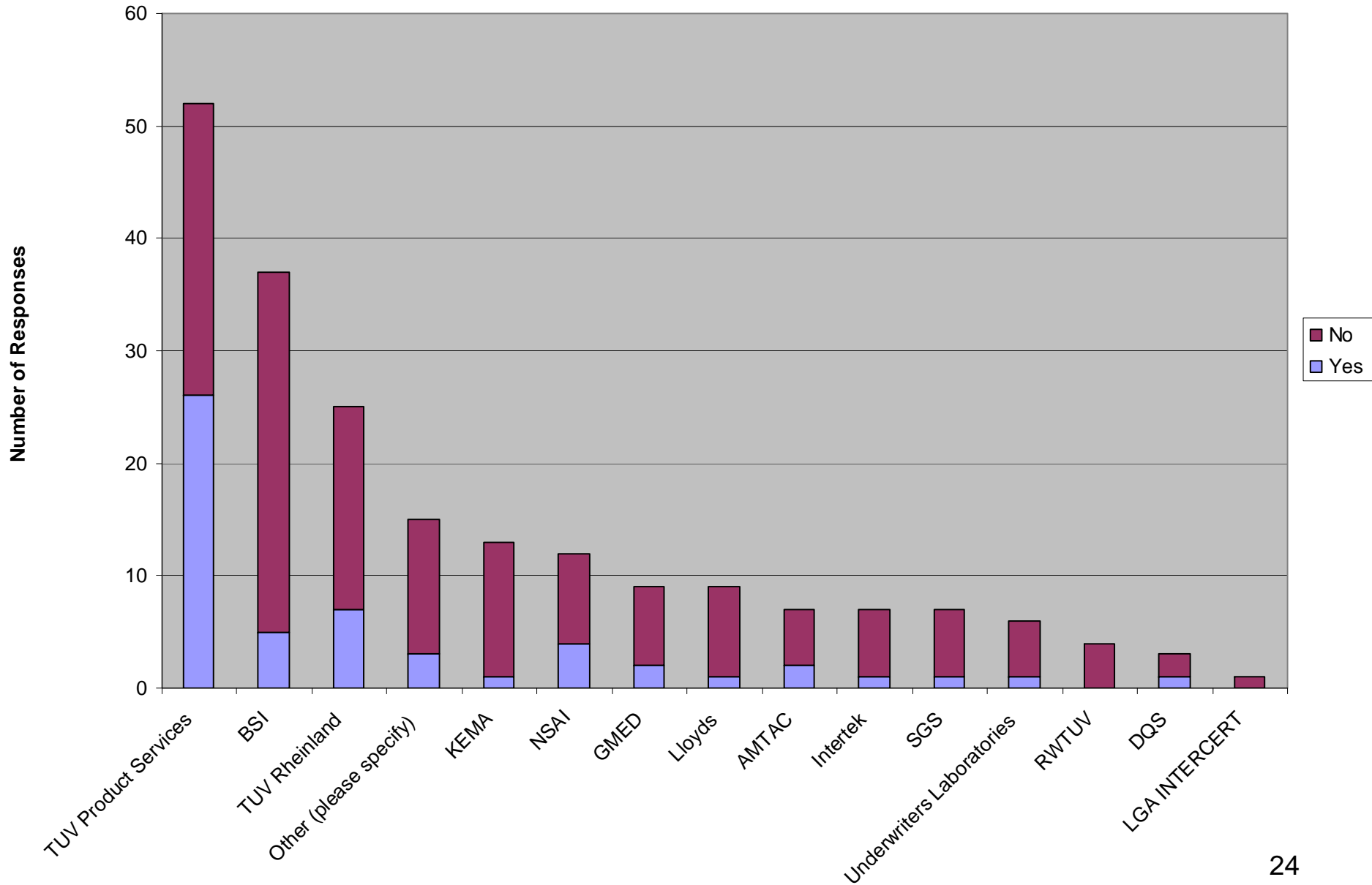
Has your notified body ever helped to identify a product safety issue prior to product launch?



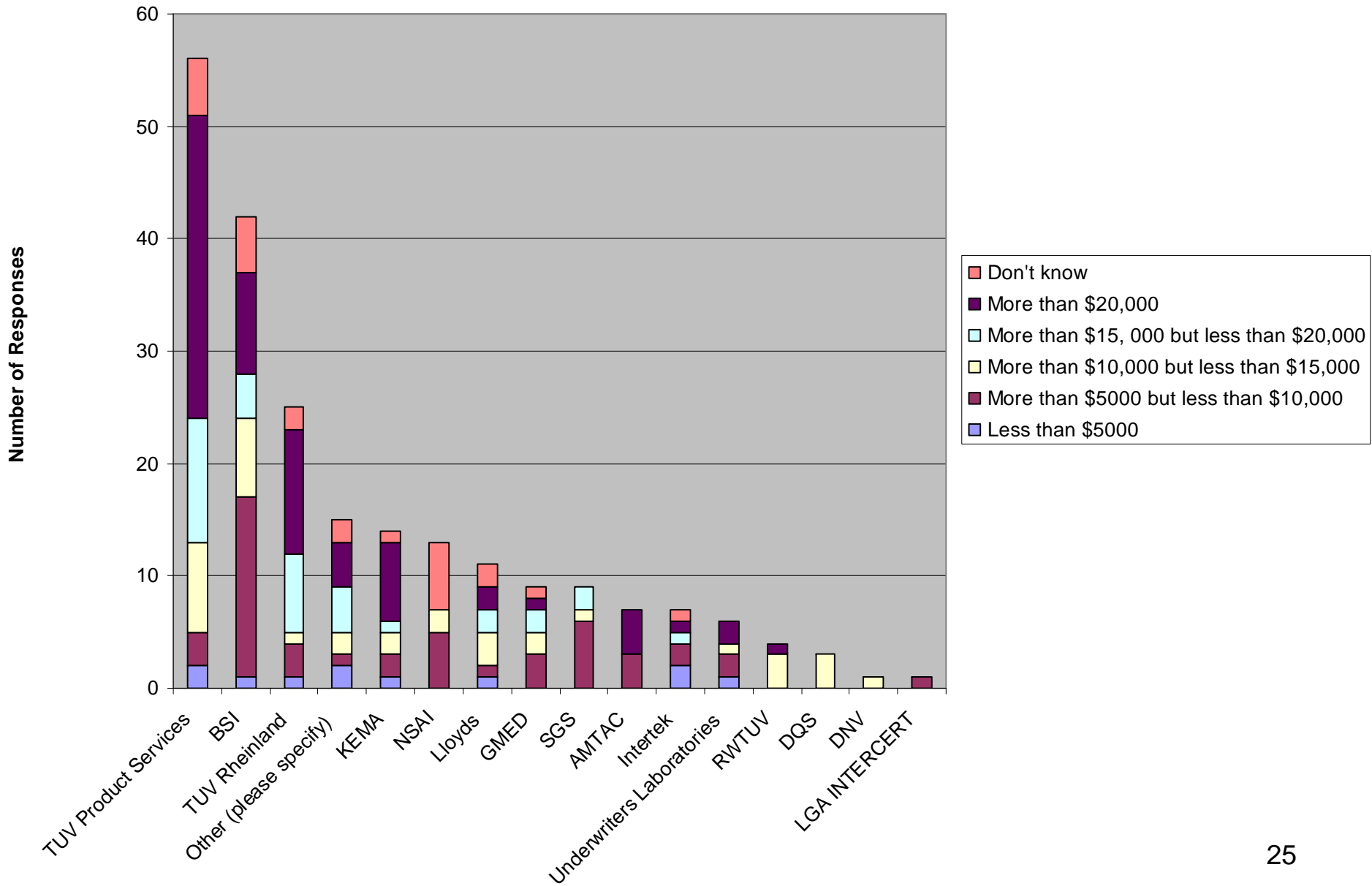
Has your notified body ever had to correct certificates prior to or after issuance?



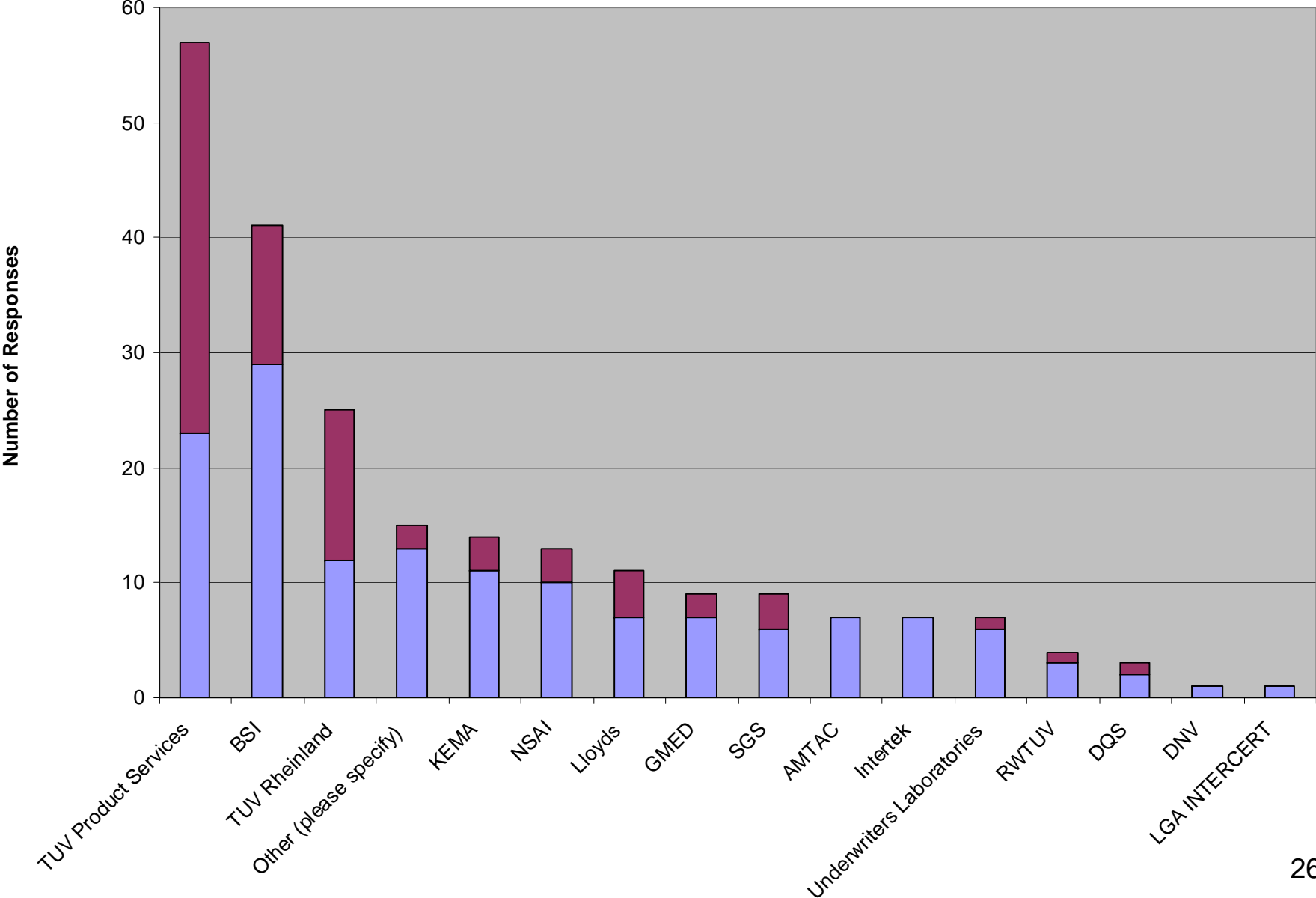
Has your notified body lost or misplaced documents during dossier review?



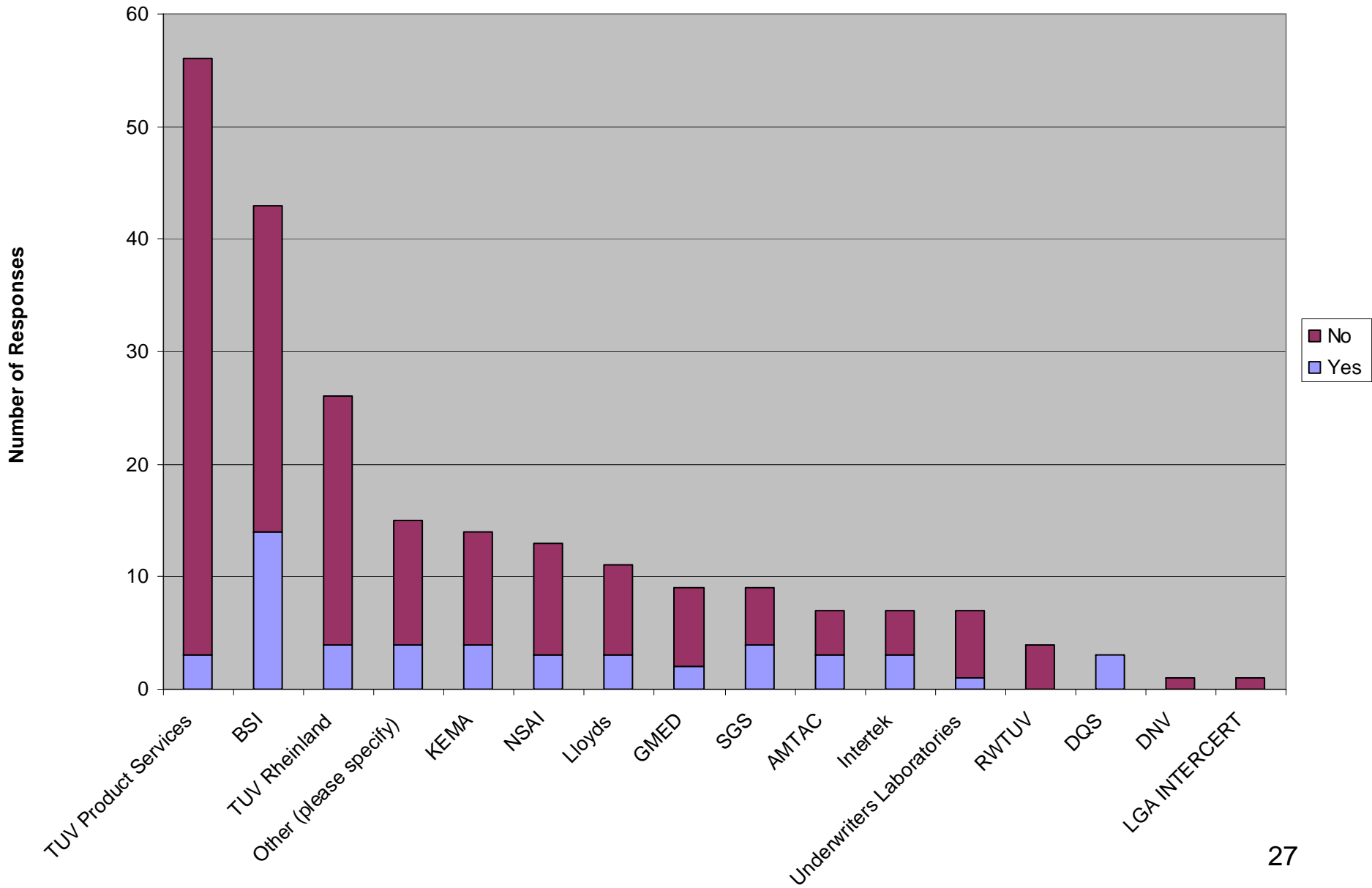
What is the average dollar amount that your firm spends on its notified body auditing program?



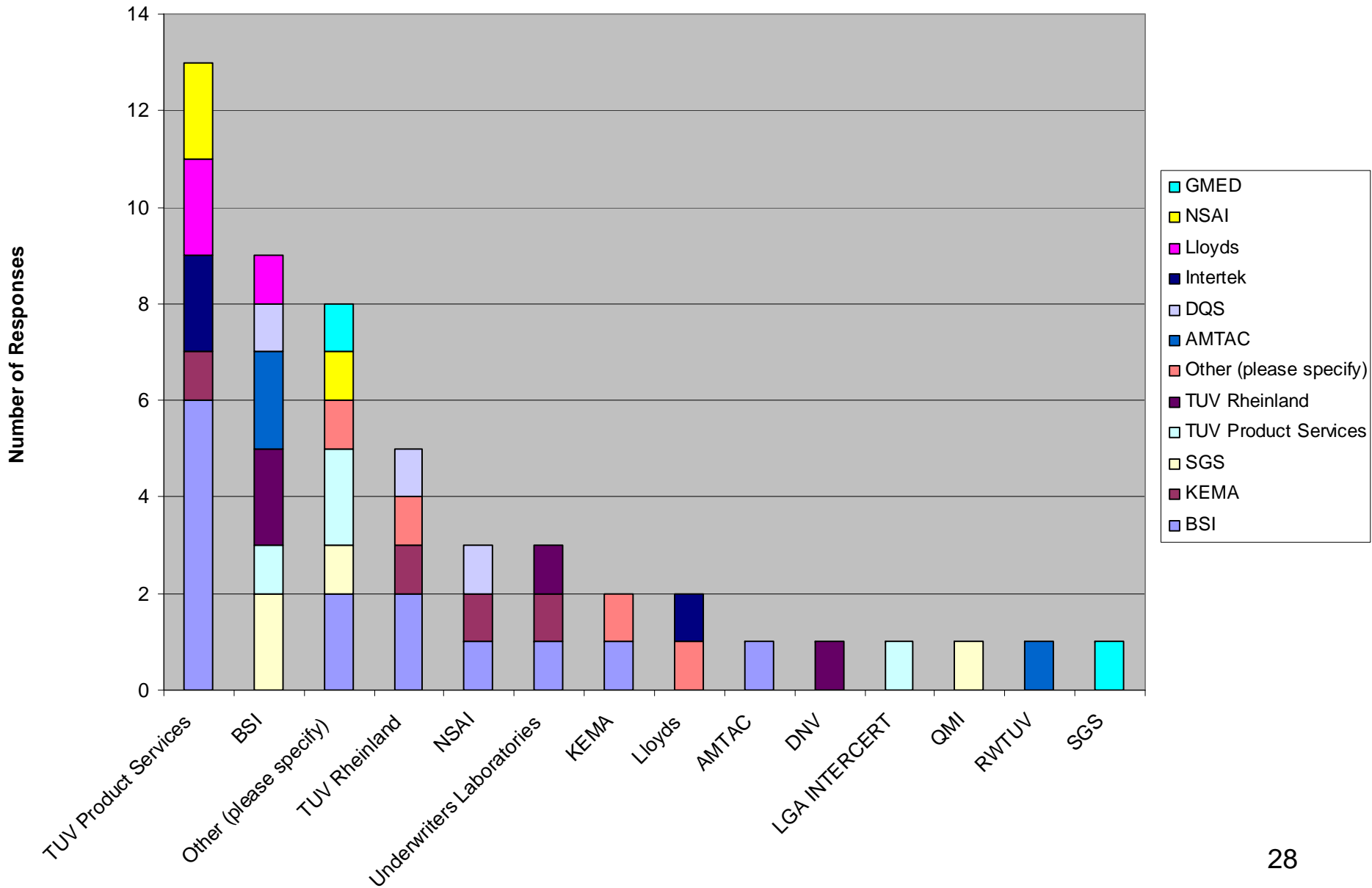
Do you believe you have gotten a positive return on your investment from your notified body audits?



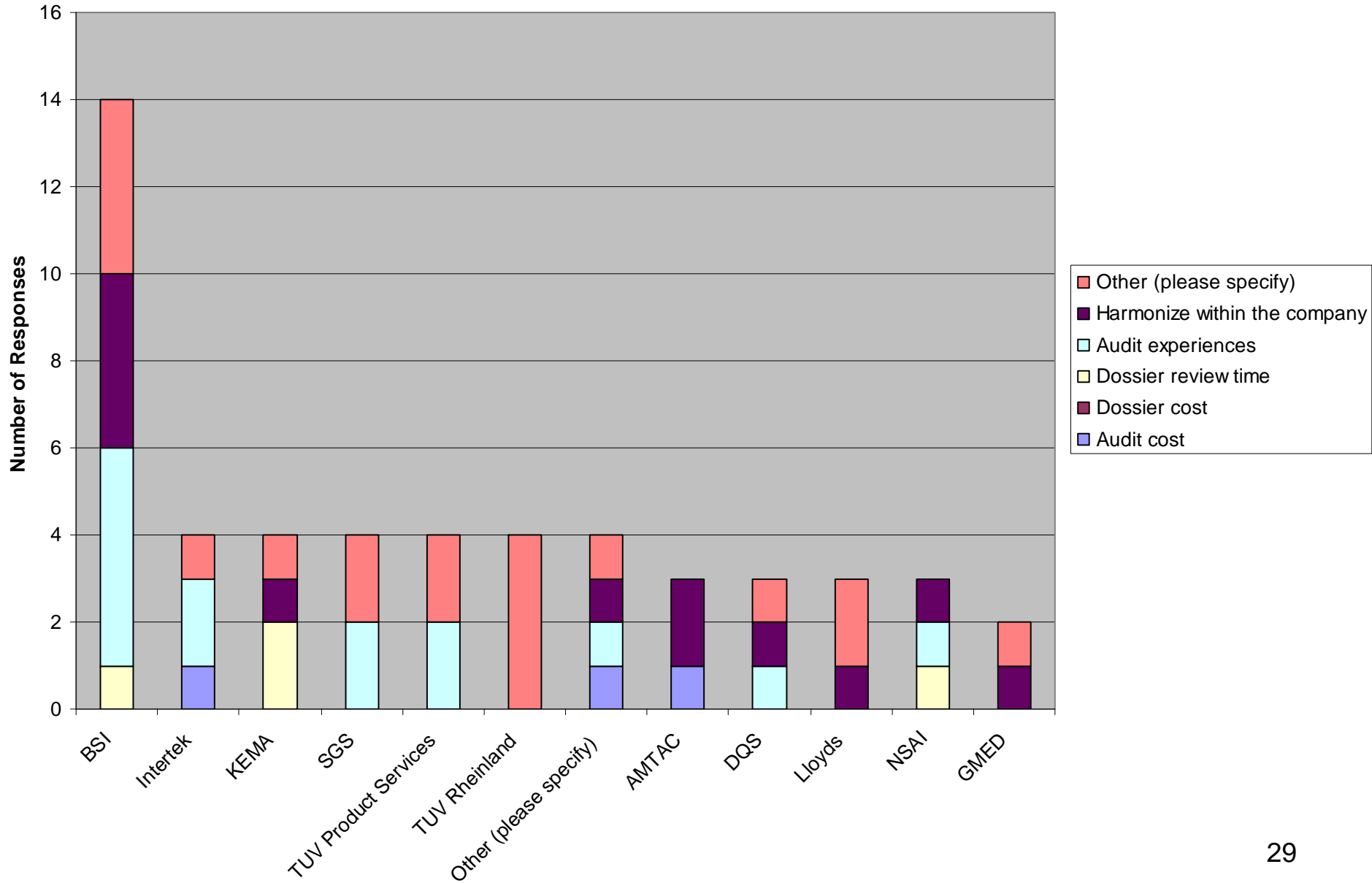
Has your firm changed notified bodies?



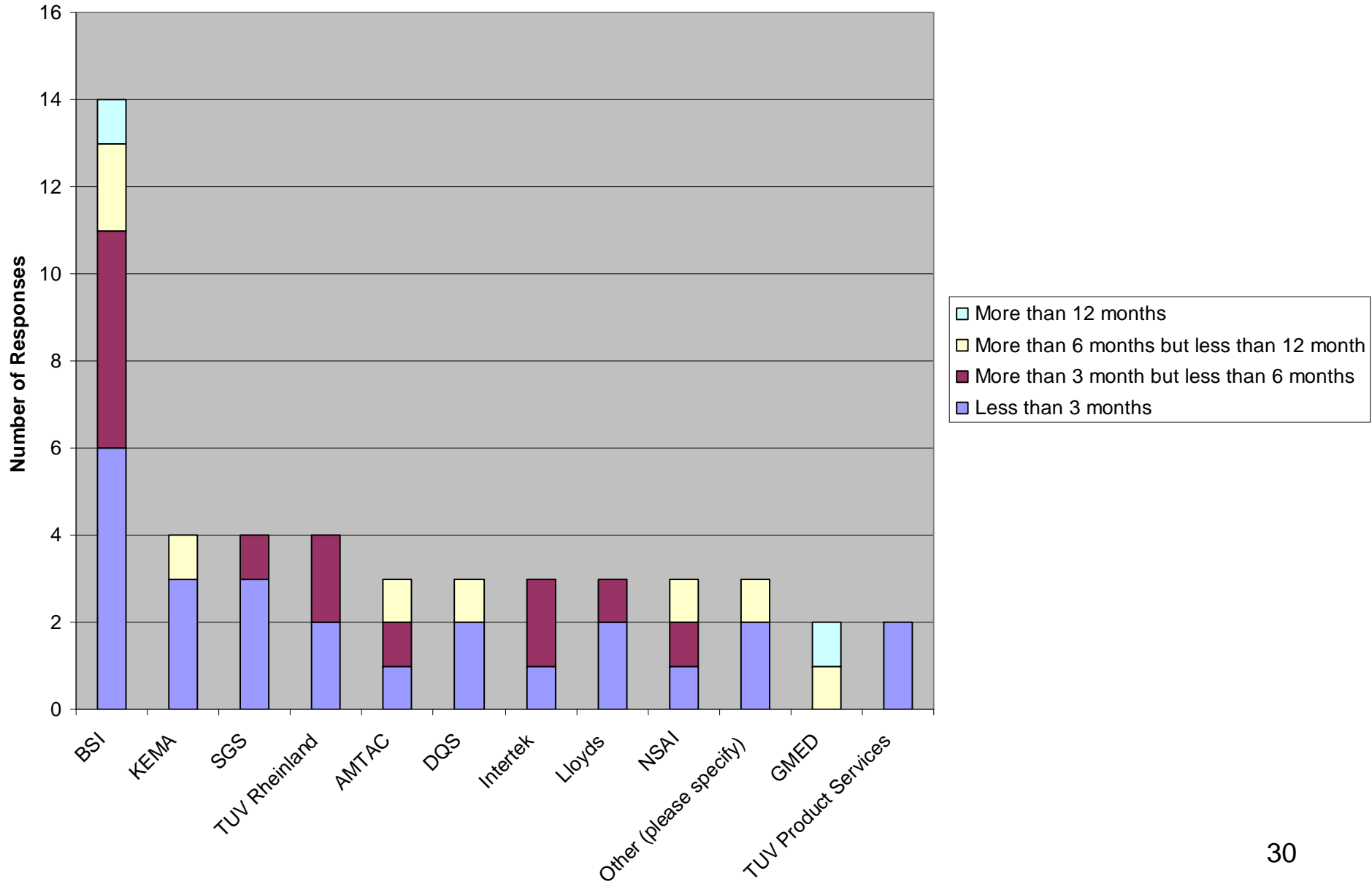
Who was the firm's prior notified body?



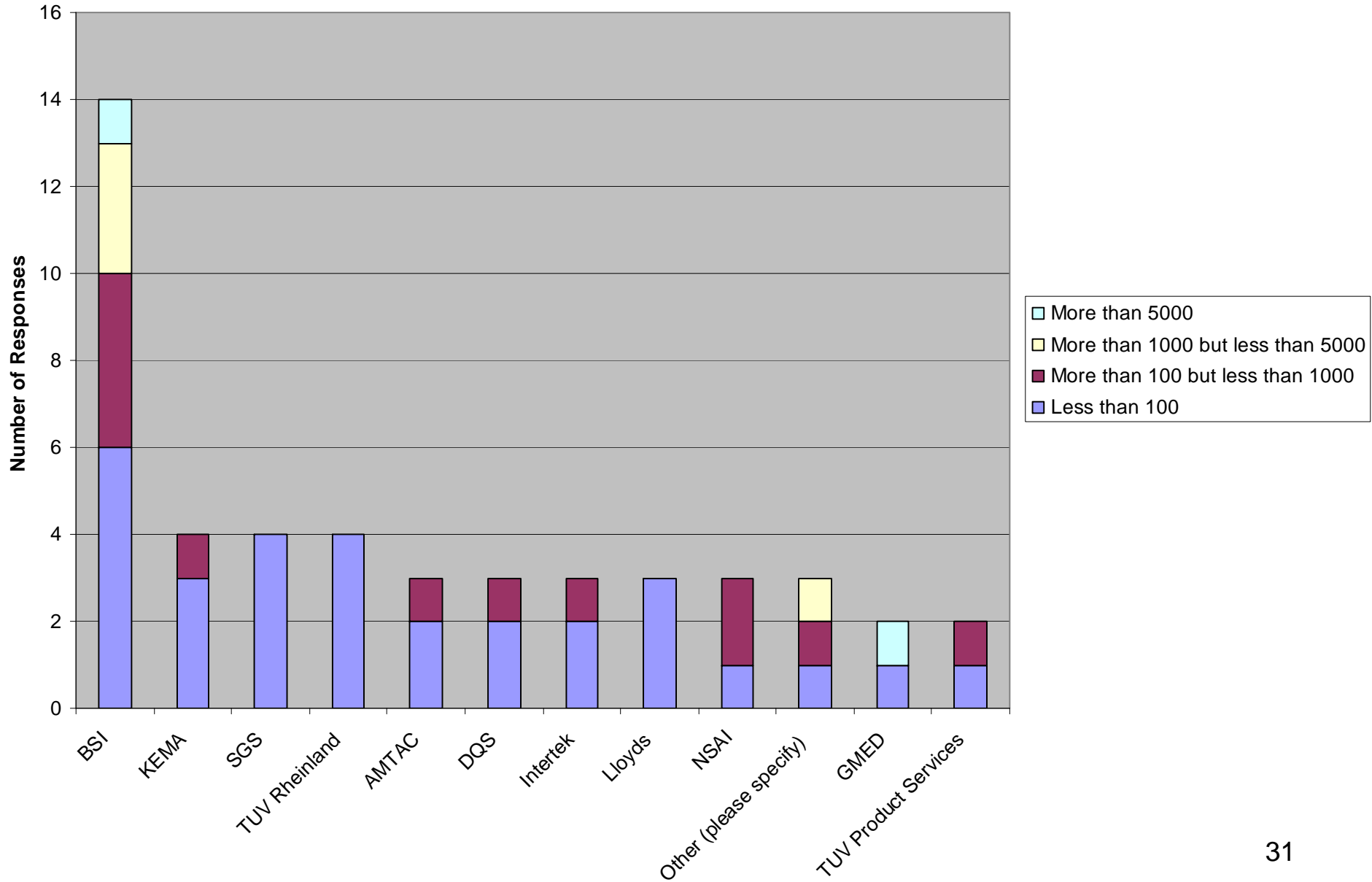
What was the most important reason that your firm changed notifiedy bodies?



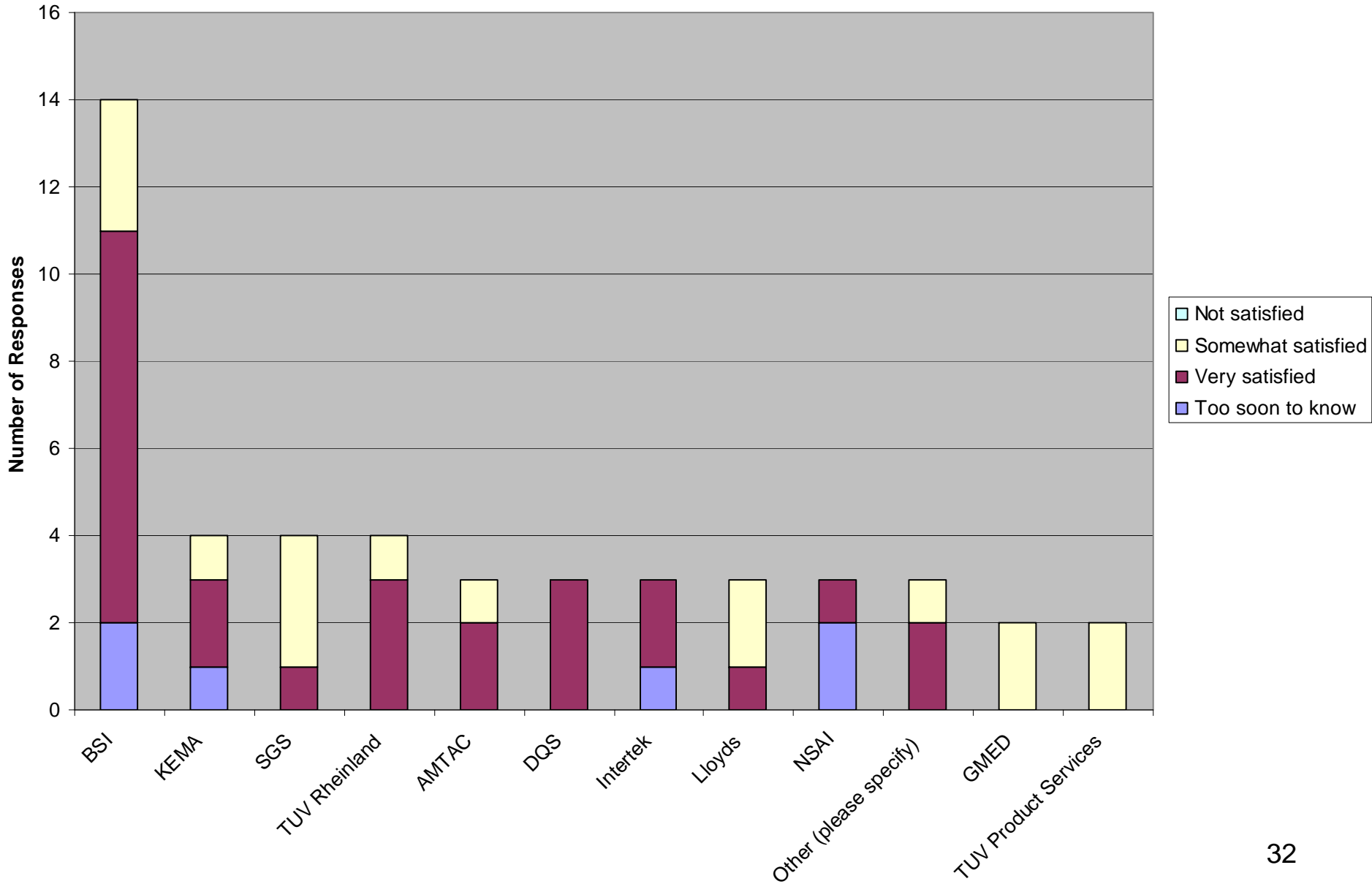
What was the transition period?



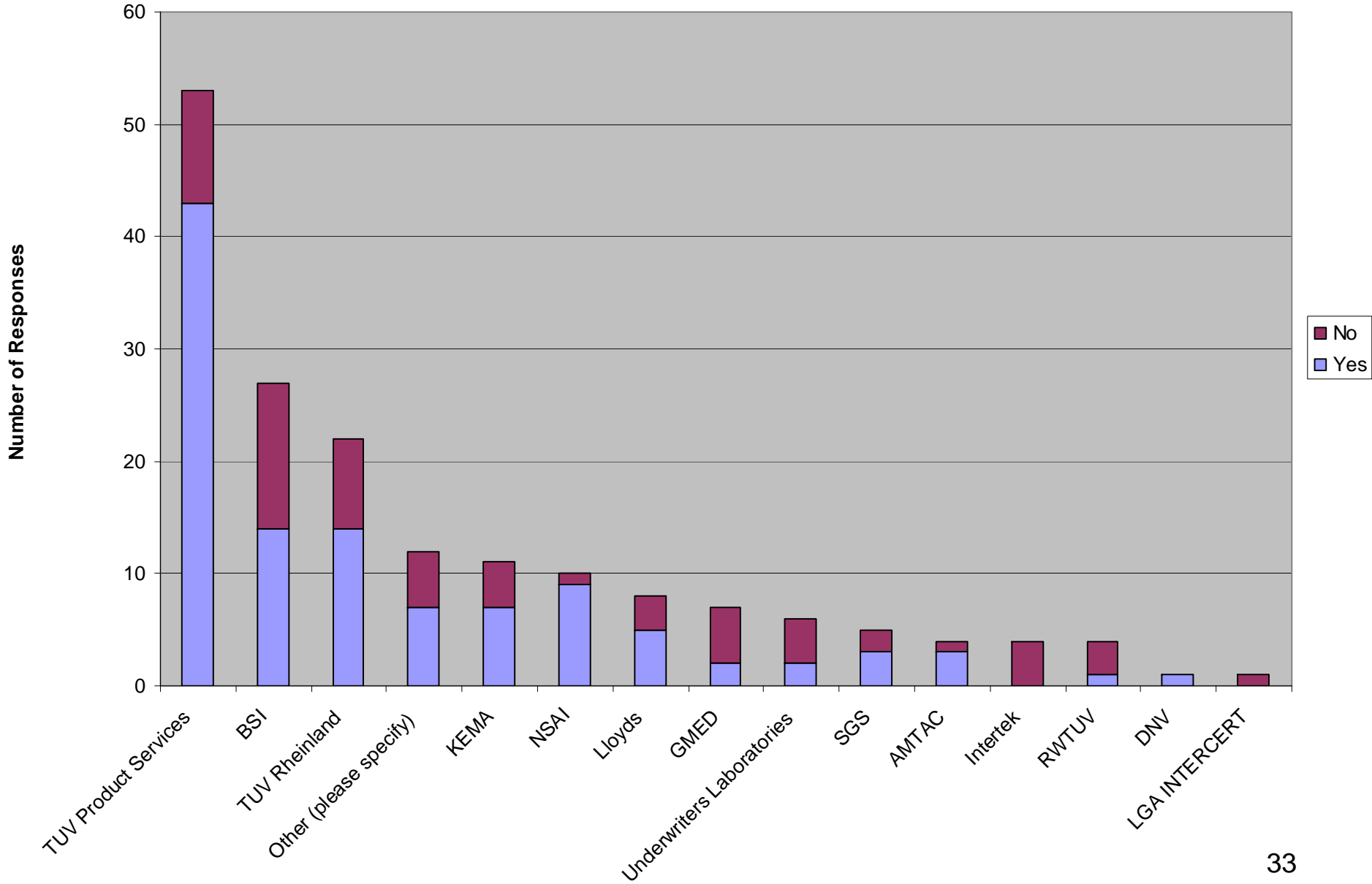
How many label/product marking changes were required?



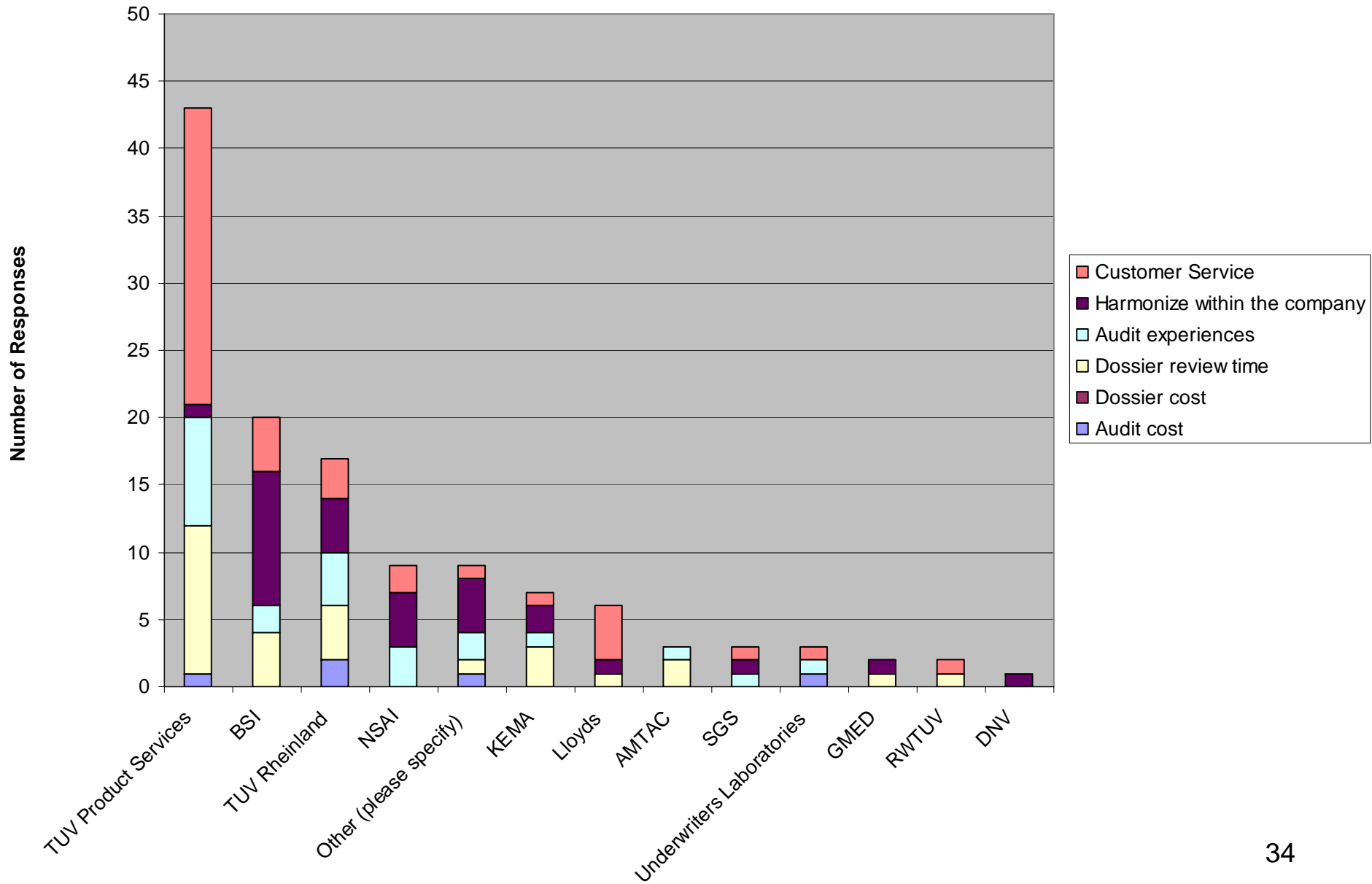
How satisfied are you with the new notified body?



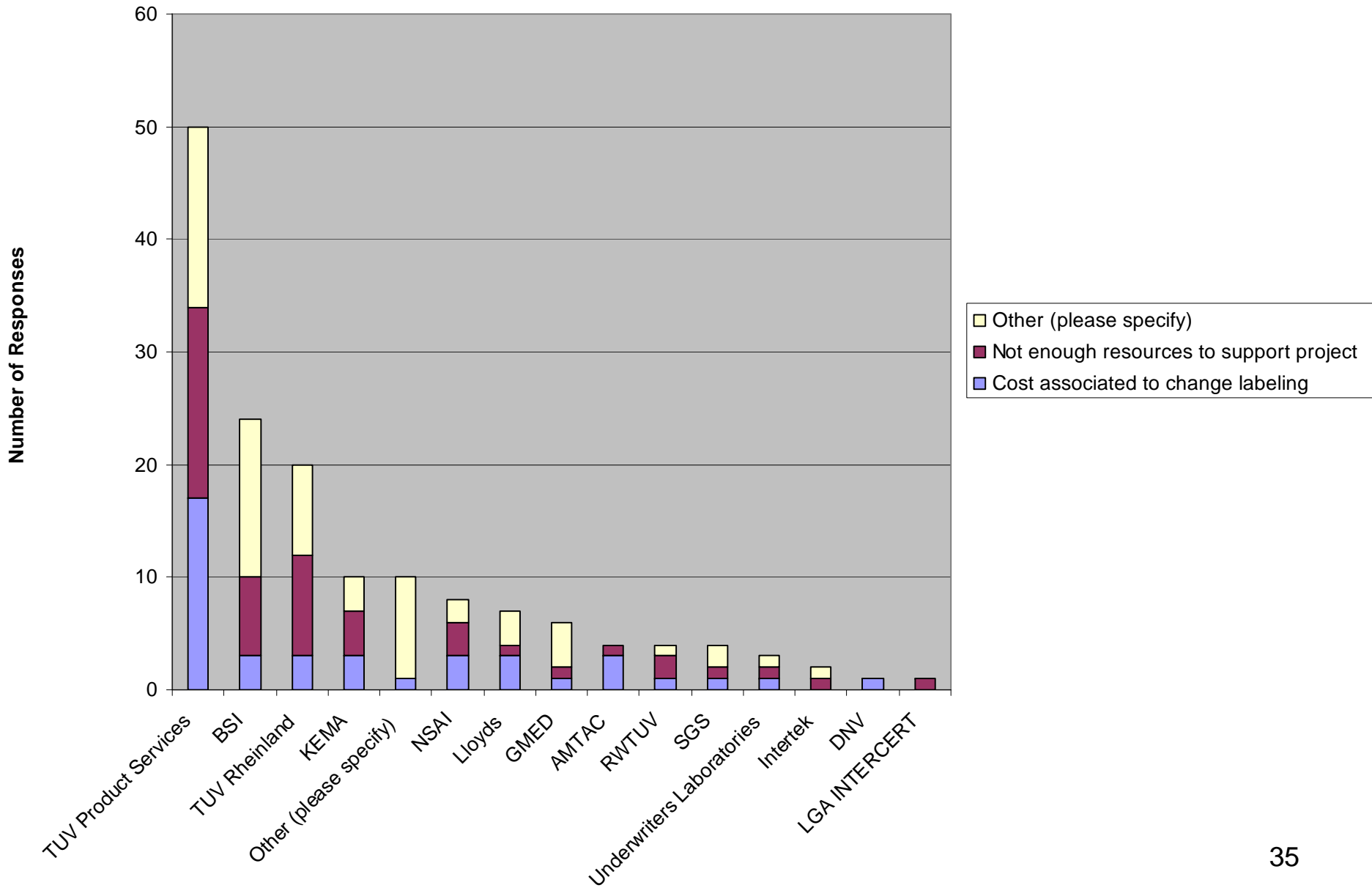
Has your firm considered changing notified bodies?



If your firm has considered changing notified bodies, what is the driving factor?



Why hasn't the company changed notified bodies



How does your notified body work with your firm? (Check all that apply.)

